Minimally-Invasive Cardiac Surgery and TAVR

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Cardiothoracic Surgery
Candidates for Minimally-Invasive Heart Surgery

• Aortic valve surgery
• Mitral valve surgery
• Surgery for atrial fibrillation = MAZE procedure
• Atrial septal defect closure
• Tricuspid valve surgery
• Removal of cardiac masses/tumors
Minimally-Invasive Aortic Valve and Mitral Valve Valve Surgery
Mini-Aortic Valve Replacement (AVR) Patient Population

• Aortic stenosis (AS)
  – Angina, Syncope, Heart failure, ↓ exercise tolerance, Lightheadedness

• Aortic regurgitation or insufficiency (AI)
  – Heart failure, Dyspnea, ↓ exercise tolerance

• Mixed AS/AI
Population at Risk for Aortic Stenosis is Increasing

Approx. 2.5 Million People in the U.S. Over the Age of 75 Suffer from Aortic Stenosis.

- Aortic stenosis is estimated to be prevalent in **12.4% of the population over the age of 75**.
- The elderly population will more than double to 80 million between now and the year 2050.
- 80% of adults with symptomatic aortic stenosis are male.

Image and content courtesy of Edwards Lifesciences
Symptomatic Aortic Stenosis Patients Require Urgent Attention

“Surgical intervention should be performed promptly once even ... minor symptoms occur”
Undertreatment of Aortic Stenosis

- At least 40% of patients who need valve replacement do not get treatment
Standard Therapy is an Ineffective Treatment for Severe Aortic Stenosis

- Without treatment, 94% of patients in the standard therapy group died within 5 years.
- With TAVR, there was a 21.8% reduction in mortality at 5 years.

Standard therapy includes medical management and BAV.

Image and content courtesy of Edwards Lifesciences.
Rehospitalization: Standard Therapy vs. TAVR

Standard therapy patients were rehospitalized TWICE as often as TAVR patients.

- With standard therapy 87.3% of patients were rehospitalized for cardiac issues.
- With TAVR there was a 39.7% reduction of rehospitalization at 5 years.

Standard therapy includes medical management and BAV.

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Image and content courtesy of Edwards Lifesciences
Mitral Valve Repair or Replacement

Patient Population

- Mitral insufficiency
  - Mitral Valve Prolapse
  - Infective Endocarditis
  - Ischemic Disease
  - Mitral Annular Dilatation
- Mitral stenosis
Mini-Mitral Valve Repair (MVR)
Patient Population

Carpentier Classifications of Mitral Insufficiency

Type I                         Type II                         Type III
Mitral Insufficiency
Reduced Survival with Medical Management

Cardiac events among patients with asymptomatic mitral regurgitation and medical management according to effective regurgitant orifice (ERO)
Surgical Options for Valve Repair and Replacement
Traditional Heart Surgery via Sternotomy
PLACEMENT OF INCISIONS DURING HEART VALVE SURGERY

AORTIC VALVE SURGERY
Incision is below right clavicle and above right nipple.

MITRAL AND INTRACUSPID VALVE SURGERY
Incision is below right nipple.
Potential Benefits of Minimally-Invasive Approach

- No division of the sternum
- Reduced trauma and pain
- Decreased blood loss
- Decreased wound infection
- Reduced recovery time
- Better cosmetics and improved patient satisfaction
- No difference in morbidity and mortality
Minimally-Invasive Aortic Valve Replacement

- Right Anterior Thoracotomy
- Hemi-sternotomy
Diseased Aortic Valve
Placement of Prosthetic Valve
Mitral Valve Repair
Mitral Valve Repair
Mini-Valve Surgery
Postoperative Pathway

- Hospital stay approximately 3-4 days
- Most patients back to work or regular activity in 2-3 weeks
Future Advancements in Minimally-Invasive Valve Surgery

Rapid-deployment, Sutureless AVR
Rapid-Deployment AVR

Short cross-clamp time demonstrated in isolated and concomitant AVR procedures in the prospective, multi-center TRANSFORM trial!

Shorter cross-clamp times generally lead to reduced complications and hospital utilization rates.

**Cross-clamp time, AVR only**

<table>
<thead>
<tr>
<th>TRANSFORM trial**</th>
<th>STS Database**</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=221)</td>
<td>(n=27,205)</td>
</tr>
<tr>
<td>49±27</td>
<td>76±28</td>
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</table>

**Cross-clamp time, AVR + CABG**

<table>
<thead>
<tr>
<th>TRANSFORM trial**</th>
<th>STS Database**</th>
</tr>
</thead>
<tbody>
<tr>
<td>(n=89)</td>
<td>(n=6,778)</td>
</tr>
<tr>
<td>67±26</td>
<td>95±31</td>
</tr>
</tbody>
</table>

**Full sternotomy**

*Single graft

**Complications**

- **Mortality**
  - ≤ 60: 2%
  - > 60-90: 5%
  - > 90: 8%

- **Prolonged ventilation**
  - ≤ 60: 4%
  - > 60-90: 6%
  - > 90: 15%

**Utilization**

- **ICU days**
  - ≤ 60: 1.9
  - > 60-90: 2.5
  - > 90: 3.5

**Blood transfusions**

- ≤ 60: 44%
- > 60-90: 47%
- > 90: 70%

**Renal complications**

- ≤ 60: 6%
- > 60-90: 9%
- > 90: 12%

**Hospital days**

- ≤ 60: 7.8
- > 60-90: 8.7
- > 90: 13.6

†Refer to Table 13 in product’s instructions for Use

‡In both low- and high-risk cardiac surgery
Transcatheter Aortic Valve Replacement
TAVR
A New Era in Treatment Options
TAVR
Clinical Considerations

• Indications
  – Prohibitive surgical risk

• Advantages
  – Short procedure
  – Rapid recovery
  – Less physiologic stress

• Disadvantages
  – Significant complication rate
  – Historically very limited patient population

• Complications
  – Peripheral vascular injury
  – Aortic dissection
  – Stroke
  – Heart block
  – Perivalvular leak
  – Coronary artery occlusion
  – Structural cardiac injury
TAVR is Equivalent to Surgery in High-risk Patients

Mortality: SAVR vs. TAVR

- At 5 years patients that had TAVR showed survival equivalent to SAVR
At both 1 and 5 year follow up, **85% of patients** treated with TAVR were in **NYHA Class I or II** compared to only **6% at baseline**.
Necessities for Launching a Successful New TAVR Program

• Heart Valve Team
  – Interventional Cardiology, CT Surgery, Cardiac Anesthesia, Cardiology Imaging, Coordinator
  – Integration of OR and Cath Lab
• Heart valve clinic/meeting
• Structural heart interventions (BAV)
• Robust surgical valve and minimally-invasive valve program as well as referral pattern
• Hospital Administration and Nursing support
• Echo alert system
Roper’s TAVR Journey

• 100% procedural success rate since start in December 2014
  – 0% need for unplanned Bypass or Sternotomy

• 69 cases done in 1st year, making Roper the fastest growing TAVR program in South Carolina

• 131 cases completed as of November 21, 2016
  – Transfemoral: 108 (includes 22 percutaneous access)
  – Transaortic: 9
  – Transapical: 5
  – Subclavian: 8
  – Open: 1
  – Valve-in-valve: 11 (includes a ViV TAVR and ViV Mitral)
TAVR Valves

SAPIEN Valve
23 and 26 mm

SAPIEN XT Valve
23, 26, 29 mm

SAPIEN 3 Valve
20, 23, 26, 29 mm

CoreValve® Evolut® R Transcatheter Aortic Valve

Model Number: EvolutR-23
Size: 23mm
Aortic Annulus
Diameter: 17*/18-20mm

Model Number: EvolutR-26
Size: 26mm
Aortic Annulus
Diameter: 20-23mm

Model Number: EvolutR-29
Size: 29mm
Aortic Annulus
Diameter: 23-26mm

CoreValve Transcatheter Aortic Valve

Model Number: MCS-P3-31-AOA-US
Size: 31mm
Aortic Annulus
Diameter: 26-29mm

Images and content courtesy of Edwards Lifesciences and Medtronic
Case Review

89yo NYHA class III

- **LVEF**: 45-50%
- **CAD**: RCA with 60-70% stenosis
- **Carotid US**: RICA and LICA 50-69%
- **PFT**: FVC = 2.79 (131% of predicted), FEV1 = 2.09 (132% of predicted); Interpretation: Normal
- **Hx**: HTN, CAD s/p 4 stents (‘01 and ’09), BAV (3/2014), hypercholesterolemia, NIIDM, ESRD on HD, COPD, diastolic HF, PVD

**STS score**: 23.5%

**Access**: Left Subclavian

**Valve**: Medtronic 29mm Evolut R

<table>
<thead>
<tr>
<th>Echo Variable (TTE)</th>
<th>Measurements</th>
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<tbody>
<tr>
<td>Trileaflet Valve</td>
<td>Y</td>
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<tr>
<td>Max AoV Velocity</td>
<td>4.76</td>
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<tr>
<td>Peak AoV Gradient</td>
<td>90.8 mmHg</td>
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<tr>
<td>Mean AoV Gradient</td>
<td>46.9 mmHg</td>
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<tr>
<td>AVA</td>
<td>0.45 cm²</td>
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<tr>
<td>Severity of AI</td>
<td>None</td>
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<tr>
<td>Severity of MR</td>
<td>None</td>
</tr>
<tr>
<td>Severity of TR</td>
<td>None</td>
</tr>
<tr>
<td>RVSP</td>
<td>n/a</td>
</tr>
<tr>
<td>EF</td>
<td>45-50%</td>
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</tbody>
</table>
Case Review

69yo  NYHA class IV

- **LVEF**: 45-50%
- **CAD**: distal subsection of LMCA with 40% stenosis
- **Carotid US**: RICA and LICA 1-15%
- **PFT**: pt. refused
- **Hx**: HTN, hyperlipidemia, HF, previous AVR with patch root enlargement and MVR (‘11), DM, stomach ulcers, breast CA s/p bilat mastectomy, CVA, Jehovah’s witness

**STS score**: 13.9%

**Access**: Transapical

**Valve**: (Aortic) Edwards 23mm XT  
(Mitral) Edwards 26mm XT

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<tbody>
<tr>
<td>Trileaflet Valve</td>
<td>Y</td>
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<tr>
<td>Max AoV Velocity</td>
<td>3.8 m/s</td>
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<tr>
<td>Peak AoV Gradient</td>
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<tr>
<td>Mean AoV Gradient</td>
<td>43 mmHg (per cath)</td>
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<tr>
<td>AVA</td>
<td>0.85 cm2</td>
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<tr>
<td>Severity of AI</td>
<td>None</td>
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<tr>
<td>Severity of MR</td>
<td>Mild-moderate</td>
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<tr>
<td>Severity of TR</td>
<td>Moderate</td>
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<tr>
<td>RVSP</td>
<td>52.8</td>
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<tr>
<td>EF</td>
<td>45-50 %</td>
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</tbody>
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30 Day Mortality: PARTNER Trials and Roper

For Roper, All-Cause Mortality was 0% in 2014 and 2.9% in 2015 at 30 days.

In the Partner II Trial, All-Cause Mortality was 1.6% and Cardiovascular Mortality was 1.0% at 30 days.

Image and content courtesy of Edwards Lifesciences
Low Stroke at 30 days
The PARTNER II Trial: SAPIEN 3 and Roper

- PARTNER II Trial: Disabling stroke was 0.8% (n=491)
- Roper 2014: Disabling stroke was 0% (n=5)
- Roper 2015: Disabling stroke was 1.5% (n=68)
Extremely Low Vascular or Bleeding Complications at 30 Days

<table>
<thead>
<tr>
<th></th>
<th>SAPIEN 3 Valve HR TF</th>
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<tbody>
<tr>
<td>Events (%)</td>
<td>(n = 491)</td>
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<tr>
<td>Major Vascular Comps.</td>
<td>5.3</td>
</tr>
<tr>
<td>Bleeding – Life Threatening</td>
<td>5.5</td>
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<table>
<thead>
<tr>
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<td>Events</td>
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<td>(n=68)</td>
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In 1 year since TAVR launch, Roper increased AVR volume by 88 cases (68 TAVR and 20 surgical AVR)
Additional Benefits

• Broadened incoming referral base
• Work up discovers need for additional outgoing referrals, procedures, and testing
  – i.e. PET scans, CyberKnife, oncology referrals, etc
• TAVR Heart Team Model used as template for new Afib and Watchman program
• Solidified the need for a Hybrid OR
Expansion of Transcatheter Technology

- **Within TAVR:**
  - use of Transcaval and Transcarotid access
  - more percutaneous Transfemoral cases
  - use of Conscious Sedation
  - bringing in new valves, more companies
  - approval for Intermediate Risk

- **Other potential programs:**
  - Mitral clip
  - Awaiting news on TMVR
SAPIEN 3 Transcatheter Aortic Valve Replacement Compared with Surgery in Intermediate-Risk Patients: A Propensity Score Analysis

ACC 2016 | Chicago | April 3, 2016
The PARTNER 2A and S3i Trials
Inclusion Criteria

• **Severe AS:** Echo-derived AVA ≤ 0.8 cm² (or AVA index < 0.5 cm²/m²) and mean AVG > 40 mmHg or peak jet velocity > 4.0 m/s

• **Cardiac Symptoms:** NYHA Functional Class ≥ II

• **Intermediate Risk:**
  1. Determined by a multi-disciplinary Heart Team
  2. Using a guideline STS between 4-8%*, and
  3. Adjudicated by case review committee
Superiority Analysis
Components of Primary Endpoint (VI)

Mortality
- Weighted Difference: -5.2%
- Upper 2-sided 95% CI: -2.4%
- Superiority Testing p-value < 0.001

Stroke
- Weighted Difference: -3.5%
- Upper 2-sided 95% CI: -1.1%
- Superiority Testing p-value = 0.004

AR > Moderate
- Weighted Difference: +1.2%
- Lower 2-sided 95% CI: +0.2%
- Superiority Testing p-value = 0.0149
The PARTNER 2A and S3i Trials

Conclusions

• A rigorous propensity score analysis comparing SAPIEN 3 TAVR with surgery from PARTNER 2A in intermediate-risk patients at 1 year demonstrated:
  – Non-inferiority for the primary endpoint (composite of all-cause mortality, all stroke, or AR ≥ moderate)
  – Superiority of SAPIEN 3 TAVR for the primary endpoint, all-cause mortality, and all stroke
  – Superiority of surgery for AR ≥ moderate

• Time-to-event analyses indicated that the benefits of SAPIEN 3 TAVR occurred in the first few months, suggesting procedure-related effects
Future Expectations and Barriers for TAVR

- Design enhancements to improve valve stability during deployment
- Availability of retrievable and repositionable delivery systems
- Lower profile devices for percutaneous access
- Need further study of paravalvular leaks and aortic insufficiency
- Need further research on durability of TAVR devices