AORTIC STENOSIS AND TAVR’S IMPACT

JAEKyoung "Jae" Hong, MD, FACC, FSCAI, RPVI
Southern Oregon Cardiology
Rogue Regional Medical Center
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DISCLOSURE

• I DO NOT HAVE ANY RELEVANT FINANCIAL RELATIONSHIPS WITH COMMERCIAL INTERESTS.
OUTLINE

• MEET MRS. C
• BACKGROUND ON TAVR
  • WHAT IS IT?
  • WHY ARE WE DOING IT?
    • WHAT WE HAVE LEARNED
    • WHERE IS IT GOING?
• MRS. C’S WORK UP AND HER TAVR RESULT
• COLLABORATION AND TEAMWORK
• CONCLUSIONS/QUESTIONS

OUR PATIENT, MRS. C

HER MAIN QUESTIONS?

• IS MY BREATHING GOING TO BETTER?
• WILL BE ABLE TO GARDEN AGAIN?
• WHAT IS MY RECOVERY GOING TO BE LIKE?
PATIENT SUMMARY

• PATIENT DEMOGRAPHICS
  • 64 YEAR OLD FEMALE
  • 104 KG
  • 167.6 CM

SURGICAL HISTORY
• BAV
• ANKLE SURGERY

MEDICAL HISTORY
• AORTIC STENOSIS
• CAD
• HTN
• PULMONARY HTN
• MORBID OBESITY (BMI OF 50 KG/M² DOWN TO 37.9 KG/M²)
• HYPOXIA
• CARDIOMYOPATHY
• CHF

FRAILTY/SURGICAL RISK

GLOBAL ASSESSMENT
• COGNITIVE: ALERT AND ORIENTED X3
• SOCIAL: MARRIED, PROPERTY MANAGER
• LIVING: INDEPENDENTLY W/ HUSBAND, ACTIVELY PRACTICING VEGAN DIET W/ SIGNIFICANT WT LOSS

FRAILTY ASSESSMENT
• ADL: 4/6
• GRIP: L-6, R-12
• 5M WALK: UNABLE TO PERFORM
• ALBUMIN: 3.9
• RECENT FALL: NONE

STS SCORE
• PROCEDURE NAME: AVR + CABG
• RISK OF MORTALITY: 6.6 %
• MORBIDITY OR MORTALITY: 35.6 %
• INFECTION: 1.9 %
• LONG LENGTH OF STAY: 20 %
• PERMANENT STROKE: 1.4 %
• PROLONGED VENTILATION: 31.4 %
• RENAL FAILURE: 9 %
• REOPERATION: 10.8 %
• SHORT LENGTH OF STAY: 11.2 %

HIGH RISK CONDITIONS
• MORBID OBESITY, CARDIOMYOPATHY, CHF, PULMONARY HTN
• FRAILTY (5M, GRIP, ADLs)
  • TWO SURGICAL OPINIONS
BACKGROUND - WHAT IS TAVR?

Edwards SAPIEN XT Transcatheter Heart Valve

With the introduction of a 29 mm size and lower profile delivery system, the SAPIEN XT TAVR can treat a wider range of patients.
BACKGROUND - WHAT IS TAVR?

5 ACCESS FOR DELIVERING A CATHETER-BASED VALVE TO THE AORTIC POSITION

FEMORAL ARTERY
LEFT VENTRICULAR APEX
ASCENDING AORTA
LEFT SUBCLAVIAN ARTERY
INFERIOR VENA CAVA TO ABDOMINAL AORTA
Critical Aortic Stenosis

BACKGROUND: WHY ARE WE DOING IT?

Latent Period
(Increasing Obstruction, Myocardial Overload)

ONSET SEVERE SYMPTOMS

Circulation 1968;38:61-67
BACKGROUND: WHY ARE WE DOING IT?

• SEVERE AORTIC STENOSIS
  • MEAN GRADIENT >40 MMHG, AORTIC VELOCITY >4.0 M/S AND INITIAL AVA <0.8 CM²

• 30-40% PATIENT DO NOT UNDERGO SURGERY
  • HIGH RISK: OLDER AGE, LV DYSFUNCTION, CO-MORBIDITIES, PATIENT PREFERENCE
  • INOPERABLE

The NEW ENGLAND JOURNAL of MEDICINE

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Peterson, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*
**25% ABSOLUTE REDUCTION IN MORTALITY**
NUMBER NEEDED TO TREAT TO PREVENT ONE DEATH AT TWO YEARS =

ALL-CAUSE MORTALITY
AT 30 DAYS, 1 YEAR, AND 2 YEARS

<table>
<thead>
<tr>
<th></th>
<th>Open AVR</th>
<th>TAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death at 30 days</td>
<td>6.5%</td>
<td>3.4%</td>
</tr>
<tr>
<td>Death at 1 year</td>
<td>26.8%</td>
<td>24.2%</td>
</tr>
<tr>
<td>Death at 2 years</td>
<td>35.0%</td>
<td>33.9%</td>
</tr>
<tr>
<td>Major Stroke at 30 days</td>
<td>2.1%</td>
<td>3.8%</td>
</tr>
<tr>
<td>Stroke at 1 year</td>
<td>3.2%</td>
<td>6.0%</td>
</tr>
<tr>
<td>Stroke at 2 years</td>
<td>4.9%</td>
<td>7.7%</td>
</tr>
</tbody>
</table>
Intermediate Surgical Risk Patients
Second Generation Device

PARTNER 2

• N=2,032 INTERMEDIATE SURGICAL RISK PATIENTS
• INTERMEDIATE RISK IS DEFINED AS SOCIETY OF THORACIC SURGERY (STS) 30 DAY MORTALITY RISK OF 4-8% OR CAN BE <4.0% IF THERE WERE COEXISTING CONDITIONS THAT WERE NOT REPRESENTED IN THE RISK MODEL
• 57 CENTERS
• SAPIEN XT VALVE UTILIZED (18F AND 20F SHEATHS)
• 76% TRANSFEMORAL ACCESS
• 24% TRANSTHORACIC ACCESS
### TAVR VS SURGICAL AVR
#### 30 DAY OUTCOMES

<table>
<thead>
<tr>
<th>Event</th>
<th>TAVR (%)</th>
<th>SAVR (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death or Disabling Stroke</td>
<td>6.1%</td>
<td>8.0%</td>
<td>0.11</td>
</tr>
<tr>
<td>Death</td>
<td>3.9%</td>
<td>4.1%</td>
<td>0.78</td>
</tr>
<tr>
<td>Any Stroke</td>
<td>5.5%</td>
<td>6.1%</td>
<td>0.57</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1.2%</td>
<td>1.9%</td>
<td>0.22</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>1.3%</td>
<td>3.1%</td>
<td>0.006</td>
</tr>
<tr>
<td>New atrial fibrillation</td>
<td>9.1%</td>
<td>26.4%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>New permanent pacemaker</td>
<td>8.5%</td>
<td>6.9%</td>
<td>0.17</td>
</tr>
<tr>
<td>Major vascular complication</td>
<td>7.9%</td>
<td>5.0%</td>
<td>0.008</td>
</tr>
<tr>
<td>Aortic valve reintervention</td>
<td>0.4%</td>
<td>0%</td>
<td>0.05</td>
</tr>
<tr>
<td>Coronary obstruction</td>
<td>0.4%</td>
<td>0.6%</td>
<td>0.53</td>
</tr>
</tbody>
</table>

### TAVR VS SURGICAL AVR
#### 2 YEAR OUTCOMES

<table>
<thead>
<tr>
<th>Event</th>
<th>TAVR (%)</th>
<th>SAVR (%)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death or Disabling Stroke</td>
<td>19.3%</td>
<td>21.1%</td>
<td>0.33</td>
</tr>
<tr>
<td>Death</td>
<td>16.7%</td>
<td>18.0%</td>
<td>0.45</td>
</tr>
<tr>
<td>Any Stroke</td>
<td>9.5%</td>
<td>8.9%</td>
<td>0.67</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>3.6%</td>
<td>4.1%</td>
<td>0.56</td>
</tr>
<tr>
<td>Acute kidney injury</td>
<td>3.8%</td>
<td>6.2%</td>
<td>0.02</td>
</tr>
<tr>
<td>New atrial fibrillation</td>
<td>11.3%</td>
<td>27.3%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>New permanent pacemaker</td>
<td>11.8%</td>
<td>10.3%</td>
<td>0.29</td>
</tr>
<tr>
<td>Major vascular complication</td>
<td>8.6%</td>
<td>5.5%</td>
<td>0.006</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>1.2%</td>
<td>0.7%</td>
<td>0.22</td>
</tr>
<tr>
<td>Aortic valve reintervention</td>
<td>0.4%</td>
<td>0.6%</td>
<td></td>
</tr>
</tbody>
</table>
PARTNER 2

Death from Any Cause, According to Severity of Paravalvular Aortic Regurgitation

Overall P=0.001 by log-rank test
Hazard ratio for mild vs. none or trace, 0.95 (95% CI, 0.63–1.45); P=0.82
Hazard ratio for moderate or severe vs. none or trace, 2.83 (95% CI, 1.57–5.23); P<0.001

<table>
<thead>
<tr>
<th>Severity</th>
<th>SAVR = TAVR</th>
<th>Surgical AVR Better</th>
<th>TAVR Better</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death and Disabling Stroke</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TAVR w/ Transfemoral Artery Approach</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>TAVR w/ Transthoracic Approach</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal Injury</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Vascular Complication</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Hospital Length of Stay</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Paravalvular Aortic Regurgitation</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Valve Area and Gradient</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SUMMARY: SAVR VS TAVR AT 2 YRS

Partner 2 Trial NEJM 2016;374:1609-20
WHERE ARE WE GOING?

- FDA APPROVAL FOR INTERMEDIATE SURGICAL RISK
- CLINICAL TRIAL IN PROGRESS FOR LOW SURGICAL RISK PATIENTS

APPROVED IN DEVELOPMENT

- Sapien XT™
- Sapien 3™
- CoreValve™
- CoreValve Evolut™
- Portico™
- Direct Flow™
- Lotus™
- Accurate™
- JenaValve™
- Engager™
BACK TO MRS. C AND HER WORKUP

ECHOCARDIOGRAPHY
ECHOCARDIOGRAPHY

- LONG AXI3 ANNULAR MEASUREMENT
- VELOCITY 3.4 M/S
- 22MM

CORONARY ANGIOGRAPHY

LCA  

RCA
CTA CARDIAC

RCA = 13.1mm Above AV ring
LM = 15.6mm Above AV ring

CTA CARDIAC

Annular Area Measurement: 480-530mm²  Working angle: LAO 7  Caudal 3
Mean: 24.3-25.6mm  Perimeter: 76mm
**Hx:** AS, CAD, HTN, pulm HTN, morbid obesity, hypoxia, cardiomyopathy, CHF, BAV

**Ankle sx**

**Cath**
- Coro: 80% LAD, 80% diag, 50% RCA, 30% Cx
- EF: 30%
- PA: 87/51 mmHg
- PCWP: 46 mmHg
- LVEDP: 38 mmHg
- AoV mean grad: 30 mmHg
- AOA: 0.57 cm²
- Index: 0.23 cm²/m²

**Echo**
- LVEF: 20%
- AoV peak vel: 4.4 m/s
- AoV peak grad: 160 mmHg/LM Ht 15.6 mm
- AoV mean grad: 160 mmHg/LM Ht 13.1 mm
- AOA: 0.8 cm²
- Index: 0.4 cm²/m²
- AR: T+ MR: 2+ TR: 1+
- Global hypokinesis
- Mild bialtrial enlargement
- Pulmonary HTN
- Moderate LVH

**CT**
- Anulus: 480-530 mm²
- Diameter: 24.3-25.6 mm
- Perimeter: 76 mm
- Coronary Distance: LM: 15.6 mm RCA: 13.1 mm
- Llloifemoral MLD:
  - RCI: 7.8 mm
  - LCI: 7.3 mm
- RCI: 5.5 mm
- LCI: 6.3 mm
- RCF: 6.9 mm
- LCF: 7.3 mm

**Procedural Plan:** Transfemoral TAVR

**Annulus Area Measurement** | **Annulus Perimeter** | **CoreValve Size Proposed** | **Femoral Access Side Proposed** | **Smallest Vessel Diameter Measurement**
--- | --- | --- | --- | ---
480-530 mm² | 76 mm | 29 mm Evolute | Left | 6.3 mm

**Comments:**
- Risk Adjudication: High Risk based on frailty (5M, grip, ADL’s), Pulmonary HTN, severe systolic heart failure
- Bailout plan: Open chest
- Pre-existing RBBB: no, LBBB (EP crew aware of possible Bi-V pacer need)
- Anti-coagulation: No
- PA catheter: Yes
WHAT ARE THE CMS REQUIREMENTS FOR A TAVR PROGRAM?

- TWO CT SURGEONS HAVE INDEPENDENTLY EXAMINED THE PATIENT FACE-TO-FACE
- INTERVENTIONAL CARDIOLOGIST HAS EVALUATED THE PATIENT FACE-TO-FACE
- MULTIDISCIPLINARY HEART TEAM INVOLVED IN PRE- AND POST-OPERATIVE CARE OF PATIENT
- ON-SITE HEART VALVE SURGERY PROGRAM
- HYBRID OPERATING ROOM
- CT, TEE, VASCULAR ULTRASOUND
WHAT ARE THE CMS REQUIREMENTS FOR A TAVR PROGRAM?

Cardiothoracic surgeon
≥100 career AVRs including 10 high-risk patients
≥25 AVRs in one year
≥50 AVRs in 2 years

Interventional Cardiologist
Professional experience with 100 structural heart disease procedures lifetime
OR
30 left sided structural procedures per year of which 60% should be balloon aortic valvuloplasty

Echocardiographers, anesthesiologists, radiologists, intensivists

Device specific training
CONCLUSIONS

- AORTIC STENOSIS IS THE MOST COMMON VALVE DISORDER IN THE U.S. AND EUROPE
- NO EFFECTIVE MEDICAL THERAPY
- SURGICAL AORTIC VALVE REPLACEMENT HAS BEEN THE STANDARD OF CARE
- MANY PATIENTS ARE INCREASED RISK FOR OPEN HEART SURGERY
- TRANSCATHETER AORTIC VALVE REPLACEMENT HAS BEEN PROVEN TO BE EFFECTIVE IN THESE PATIENTS

QUESTIONS