TAVR: What Have Cardiologists Have Learned from the Cardiac Surgeons?

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Harvard Medical School
Director, Interventional Cardiology
Clinical Services
Beth Israel Deaconess Medical Center
Boston, MA
Conflict of Interest Statement

Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Physician Name</th>
<th>Company/Relationship</th>
</tr>
</thead>
</table>

Disclaimer: “Caution – CoreValve TAVR is an investigational devices, limited by United States to Investigation use only.”
What Have Cardiologists Learned From Surgeons?

- TAVR Fundamentals
- “Multidisciplinary teams” and collaborations
- STS PROM is limited as a calibrated index for outcome in elderly patients with “High Risk” AS
  - “Extreme Risk” and “STS Plus”
- The Aortoavalvular Complex
  - Residual Paravalvular Regurgitation, PPM
- Hybrid ORs: A necessity not extravagance
- Alternative Access Routes
  - Making Interventionalist think like surgeons
Dr. Alain Cribier: First-in-Man PIONEER

April 16, 2002

Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis
First Human Case Description
Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumeaux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD

Anterograde Approach
1st Generation SAPIEN

AHA: Nov, 2002
EDWARD SAPIEN – Commercially Approved

Edwards-SAPIEN THV

23mm and 26mm valve sizes

Retroflex 1

22F and 24F sheath sizes
Building The Clinical Evidence Base

PARTNER B

TAVR v. Medical therapy

Leon NEJM 2010;363:1597-607

PARTNER A

TAVR v. SAVR

Smith NEJM 2011;364:2187-98.

Standardized Endpoint Definitions for Transcatheter Aortic Valve Implantation Clinical Trials
A Consensus Report From the Valve Academic Research Consortium

Leon J Am Coll Cardiol 2011;57:253–69
PARTNER Study Design

Symptomatic Severe Aortic Stenosis

ASSESSMENT: High Risk AVR Candidate
3105 Total Patients Screened

Total = 1058 patients

2 Parallel Trials: Individually Powered

n= 700
High Risk

ASSESSMENT: Transfemoral Access

High Risk TF

1:1 Randomization

TAVI Transfemoral vs Surgical AVR

Primary Endpoint: All Cause Mortality (1 yr) (Non-inferiority)

High Risk TA

1:1 Randomization

TAVI Transfemoral vs Surgical AVR

Inoperable n=358

ASSESSMENT: Transfemoral Access

1:1 Randomization

TAVI Transfemoral vs Standard Therapy (usually BAV)

Primary Endpoint: All Cause Mortality over length of trial (Superiority)

Not In Study
### PARTNER B: Patient Characteristics - 1

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>TAVI n=179</th>
<th>Standard Rx n=179</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age - yr</strong></td>
<td>83.1 ± 8.6</td>
<td>83.2 ± 8.3</td>
<td>0.95</td>
</tr>
<tr>
<td><strong>Male sex (%)</strong></td>
<td>45.8</td>
<td>46.9</td>
<td>0.92</td>
</tr>
<tr>
<td><strong>STS Score</strong></td>
<td>11.2 ± 5.8</td>
<td>12.1 ± 6.1</td>
<td>0.14</td>
</tr>
<tr>
<td><strong>Logistic EuroSCORE</strong></td>
<td>26.4 ± 17.2</td>
<td>30.4 ± 19.1</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>NYHA</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I or II (%)</td>
<td>7.8</td>
<td>6.1</td>
<td>0.68</td>
</tr>
<tr>
<td>III or IV (%)</td>
<td>92.2</td>
<td>93.9</td>
<td>0.68</td>
</tr>
<tr>
<td><strong>CAD (%)</strong></td>
<td>67.6</td>
<td>74.3</td>
<td>0.20</td>
</tr>
<tr>
<td><strong>Prior MI (%)</strong></td>
<td>18.6</td>
<td>26.4</td>
<td>0.10</td>
</tr>
<tr>
<td><strong>Prior CABG (%)</strong></td>
<td>37.4</td>
<td>45.6</td>
<td>0.17</td>
</tr>
<tr>
<td><strong>Prior PCI (%)</strong></td>
<td>30.5</td>
<td>24.8</td>
<td>0.31</td>
</tr>
<tr>
<td><strong>Prior BAV (%)</strong></td>
<td>16.2</td>
<td>24.4</td>
<td>0.09</td>
</tr>
<tr>
<td><strong>CVD (%)</strong></td>
<td>27.4</td>
<td>27.5</td>
<td>1.00</td>
</tr>
</tbody>
</table>
PARTNER B 2 Year: All Cause Mortality (ITT)

**Mortality 0-1 yr**

HR [95% CI] = 0.57 [0.44, 0.75]

p (log rank) < 0.0001

50.7%

**Mortality 1-2yr**

HR [95% CI] = 0.58 [0.37, 0.92]

p (log rank) = 0.0194

35.1%

**Numbers at Risk**

<table>
<thead>
<tr>
<th></th>
<th>TAVR</th>
<th>Standard Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 mo</td>
<td>179</td>
<td>179</td>
</tr>
<tr>
<td>1 yr</td>
<td>138</td>
<td>121</td>
</tr>
<tr>
<td>2 yr</td>
<td>124</td>
<td>85</td>
</tr>
<tr>
<td>3 yr</td>
<td>110</td>
<td>62</td>
</tr>
<tr>
<td>4 yr</td>
<td>83</td>
<td>42</td>
</tr>
</tbody>
</table>

Landmark Analysis

Makkar TCT2011 LBCT
PARTNER B TAVR Admission Costs

Index Admission Costs

- Procedure: $42,806
- Non-Procedural: $30,756
- MD Fees: $4,978

Hospital Costs: $73,563

Mean (median) LOS (days)
- ICU: 4.0 (2.0)
- Non-ICU: 6.1 (5.0)
- Total: 10.1 (7.0)
- Post-Procedure: 8.6 (6.0)

(N=175)
PARTNER B: Cost-Effectiveness of TAVR
Lifetime Results

$50,000 per LY

$100,000 per LY

$0

$100,000

$50,000

$50,000 per LY

ΔCost = $79,837
Δ LE = 1.59 years
ICER = $50,212/LYG

$0

$50,000

-50,000

-100,000

-2.5

-1.5

-0.5

0.5

1.5

2.5

↓ Cost
↓ LE

↑ Cost
↑ LE

↓ Cost
↓ LE
PARTNER Study Design

Symptomatic Severe Aortic Stenosis

ASSESSMENT: High-Risk AVR Candidate
3,105 Total Patients Screened

Total = 1,057 patients
2 Parallel Trials: Individually Powered

High Risk
N = 699

Asessment: Transfemoral Access

Yes

Transfemoral (TF)
N = 244
TF TAVR

1:1 Randomization

N = 248

Yes

Transapical (TA)
N = 104
TA TAVR

1:1 Randomization

N = 103

No

Inoperable
N = 358

ASSESSMENT: Transfemoral Access

Yes

TF TAVR

1:1 Randomization

N = 179

No

Not In Study
N = 179

Primary Endpoint: All-Cause Mortality at 1 yr
(Non-inferiority)

Standard Therapy

Primary Endpoint: All-Cause Mortality
Over Length of Trial (Superiority)
Co-Primary Endpoint: Composite of All-Cause Mortality
and Repeat Hospitalization (Superiority)
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>TAVR (N = 348)</th>
<th>AVR (N = 351)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>83.6 ± 6.8</td>
<td>84.5 ± 6.4</td>
<td>0.07</td>
</tr>
<tr>
<td>Male sex - %</td>
<td>57.8</td>
<td>56.7</td>
<td>0.82</td>
</tr>
<tr>
<td>STS Score</td>
<td>11.8 ± 3.3</td>
<td>11.7 ± 3.5</td>
<td>0.61</td>
</tr>
<tr>
<td>Logistic EuroSCORE</td>
<td>29.3 ± 16.5</td>
<td>29.2 ± 15.6</td>
<td>0.93</td>
</tr>
<tr>
<td>NYHA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II - %</td>
<td>5.7</td>
<td>6.0</td>
<td></td>
</tr>
<tr>
<td>III or IV - %</td>
<td>94.3</td>
<td>94.0</td>
<td>0.79</td>
</tr>
<tr>
<td>CAD - %</td>
<td>74.9</td>
<td>76.9</td>
<td>0.59</td>
</tr>
<tr>
<td>Previous MI - %</td>
<td>26.8</td>
<td>30.0</td>
<td>0.40</td>
</tr>
<tr>
<td>Prior CV Intervention - %</td>
<td>72.1</td>
<td>71.6</td>
<td>0.93</td>
</tr>
<tr>
<td>Prior CABG - %</td>
<td>42.6</td>
<td>44.2</td>
<td>0.70</td>
</tr>
<tr>
<td>Prior PCI - %</td>
<td>34.0</td>
<td>32.5</td>
<td>0.68</td>
</tr>
<tr>
<td>Prior BAV - %</td>
<td>13.4</td>
<td>10.2</td>
<td>0.24</td>
</tr>
<tr>
<td>Cerebrovascular disease - %</td>
<td>29.3</td>
<td>27.4</td>
<td>0.60</td>
</tr>
</tbody>
</table>
PARTNER A: All-Cause Mortality Transfemoral (N=492)

HR [95% CI] = 0.83 [0.60, 1.15]
P (log rank) = 0.25

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>TAVR</th>
<th>AVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>244</td>
<td>215</td>
<td>188</td>
</tr>
<tr>
<td>188</td>
<td>119</td>
<td>109</td>
</tr>
<tr>
<td>119</td>
<td>59</td>
<td>56</td>
</tr>
</tbody>
</table>
Index Admission Costs
Transfemoral

\[ \Delta = (2,496) \]
\[ P = 0.53 \]

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Non-Procedure</th>
<th>Total MD Fees</th>
</tr>
</thead>
<tbody>
<tr>
<td>TF-TAVR</td>
<td>$34,863</td>
<td>$14,451</td>
</tr>
<tr>
<td>$31,192</td>
<td>$4,742</td>
<td></td>
</tr>
<tr>
<td>$71,955</td>
<td>$5,773</td>
<td></td>
</tr>
<tr>
<td>$74,452</td>
<td>$54,228</td>
<td></td>
</tr>
</tbody>
</table>
FDA Advisory Panel Recommended Approval for TAVR as an alternative to sAVR in High-Risk Patients 12 to 0 (1) on Wednesday
CoreValve® Percutaneous Aortic Valve

Outflow Orientation

Constrained Portion Valve Function

Inflow Portion Sealing

1. Sits in ascending aorta
2. Orientation during deployment

1. Supra-annular leaflet function
2. Designed to avoid coronaries

1. Intra-annular anchoring
2. Mitigates paravalvular aortic regurgitation

Photograph provided by Piazza, Serruys, and DeJaegere

INTERNATIONAL Caution: For distribution only in markets where CoreValve has been approved. Not approved in the USA, Canada or Japan.
45 Participating Study Sites Activated

- High Volume Centers; Multidisciplinary Teams
- On-line course worked followed by 2 Day Product Training with Procedural Simulation
- 3 Roll-in Cases; 10 Cases Proctored Per Site
CoreValve US Trial: Completion

CoreValve U.S. Pivotal Trial

“Extreme Risk” (Up to 687)

Iliofemoral access?

No

CoreValve Observational Up to 200

Yes

CoreValve Single Arm N=487

“High Risk” N=790

Randomization 1:1*

CoreValve N=395

SAVR N=395

Enrollment Jan 2012

Projected Completion Summer 2012

Completed
New TAVR valves are coming to the market

**Today**
- Medtronic CoreValve
- Edwards Sapien
- Edwards Sapien XT

**Tomorrow**
- Next Gen. Medtronic CoreValve
- Medtronic Engager
- Edwards Sapien XT
- Boston Sci. Lotus™
- Saint Jude Portico™
- JenaValve
- HLT
- Direct Flow
- Symetis ACCURATE
What Have Cardiologists Learned From Surgeons?

- TAVR Fundamentals
- “Multidisciplinary teams” and collaborations
- STS PROM is limited as a calibrated index for outcome in elderly patients with “High Risk” AS
  → “Extreme Risk” and “STS Plus”
- The Aortoavalvular Complex
  → Residual Paravalvular Regurgitation, PPM
- Hybrid ORs: A necessity not extravagance
- Alternative Access Routes
  → Making Interventionalist think like surgeons
We are still working on the reimbursement issues – but not everyone gets paid for the work
Transcatheter Valve Therapy
A Professional Society Overview from the American College of Cardiology Foundation

Multisociety (AATS, ACCF, SCAI, and STS)
Expert Consensus Statement:
Operator and Institutional Requirements for
Transcatheter Valve Repair and Replacement,
Part 1: Transcatheter Aortic Valve Replacement

2012 ACCF/AATS/SCAI/STS Expert Consensus Document on Transcatheter Aortic Valve Replacement

Developed in collaboration with the American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Failure Society of America, Mended Hearts, Society of Cardiovascular Anesthesiologists, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance

Writing Committee Members
David R. Holmes, Jr., MD, FACC, Chair*
Michael J. Mack, MD, FACC, Vice Chair†
Sanjay Kaul, MBBS, FACC, Vice Chair*

Debabrata Mukherjee, MD, FACC*
Catherine M. Otto, MD, FACC*
Carlos E. Ruiz, MD, PHD, FACC, FSCAI§
Proper Coding Makes a Huge Difference

Only tracheostomies and cardiac transplants provide higher hospital reimbursement

- Valve Replacement with Cardiac Catheterization

<table>
<thead>
<tr>
<th>ICD-9-CM³ Diagnosis Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>424.1</td>
<td>Aortic valve disorders</td>
</tr>
<tr>
<td>35.06</td>
<td>Transapical (not currently being paid)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-9-CM³ Procedure Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>35.054</td>
<td>Endovascular replacement of aortic valve</td>
</tr>
<tr>
<td>Cardiac Catheterization</td>
<td>The cardiac catheterization may be coded when performed for specific evaluation beyond the approach during the procedure.</td>
</tr>
</tbody>
</table>

- DRG 220 (with CC)
- DRG 221 (no MCC-CC)
• Applicable to all CMS Intermediaries
• Template for commercial payers
• TAVR is covered for the treatment of symptomatic aortic valve stenosis according to an FDA approved indication and when five conditions are met
New Physician Reimbursement Codes

**PHYSICIAN INPATIENT CODING**

Clinicians use Current Procedural Terminology (CPT) Category III codes to track the use of emerging technology, services, and procedures for clinical efficacy, utilization and outcomes, and to facilitate billing. Category III codes are temporary and do not have relative value units (RVUs) assigned to them unlike the “permanent” CPT Category I codes. Payment has not been established and is therefore based on the payers’ policies rather than a yearly fee schedule.

The below procedure was assigned a Category III CPT code in July 2010 with an effective date of January 1, 2011.

<table>
<thead>
<tr>
<th>PROCEDURE</th>
<th>CPT Code¹ ²</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR – transfemoral approach</td>
<td>0256T</td>
<td>Implantation of catheter-delivered prosthetic aortic heart valve; endovascular approach. Code 0256T does not include cardiac catheterization [93451-93572] when performed at the time of the procedure for diagnostic purposes prior to aortic valve replacement. Code 0256T includes all other catheterization[s], temporary pacing, intraprocedural contrast injection[s], fluoroscopic radiological supervision and interpretation, and imaging guidance, which are not reported separately when performed to complete the aortic valve procedure.</td>
</tr>
<tr>
<td></td>
<td>Modifiers that may be allowed: assistants at surgery</td>
<td>-80</td>
</tr>
<tr>
<td></td>
<td>-81</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-82</td>
<td></td>
</tr>
</tbody>
</table>
What Have Cardiologists Learned From Surgeons?

- TAVR Fundamentals
- “Multidisciplinary teams” and collaborations
- STS PROM is limited as a calibrated index for outcome in elderly patients with “High Risk” AS
  - “Extreme Risk” and “STS Plus”
- The Aortoavalvular Complex
  - Residual Paravalvular Regurgitation, PPM
- Hybrid ORs: A necessity not extravagance
- Alternative Access Routes
  - Making Interventionalist think like surgeons
Two-thirds of patients will remain optimal surgical candidates.

- Too Sick for sAVR but OK for TAVR
- Too Sick for sAVR or TAVR
- “Eyeball Test” is very useful

Identifying the Right Patients

Surgical Aortic Valve Replacements 70-90,000 yearly

Inoperable 20-50K

Top 33% Surgical Risk
STS ≥ 4

Top 7% Surgical Risk
STS > 8

Extreme Risk

“Cohort C”

PARTNER IIA
SURTAVI

Intermediate ≈ 26%

PARTNER B
CoreValve

PARTNER A
CoreValve

High Risk

Futility

• Too Sick for sAVR but OK for TAVR
• Too Sick for sAVR or TAVR
• “Eyeball Test” is very useful
TAVR-FDA Clinical Trial Challenge

• Patients required to have critical aortic stenosis that is severe enough to impact their chance of survival over the next 12 months.
  → No Low-gradient, low-output AS, AVA < 0.8 cm²

• Patients required to have substantial (> 15%) 30-day surgical mortality risk
  → No minimum STS risk score; new risk parameters

• Patients required to have a good likelihood of surviving for the next year after their aortic stenosis has been corrected
  → Exclude “mortal” co-morbidities --- FRAILTY!
### "Extreme" and "High" On-Label Studies

<table>
<thead>
<tr>
<th>Indication</th>
<th>US CoreValve</th>
<th>US Sapien</th>
<th>ROW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endpoint</td>
<td>Death, Stroke</td>
<td>Death</td>
<td>MAE</td>
</tr>
<tr>
<td>“Inoperable” or “Extreme” Risk</td>
<td>&gt; 50% risk of 30d mortality or irreversible morbidity</td>
<td>&gt; 50% risk of either death by 30 days or a serious irreversible condition.</td>
<td>EuroSCORE &gt; 15, or 1 to 2 co-morbidities: cirrhosis, pulmonary insufficiency (forced expiratory volume in 1 s &lt;1 L), previous CABG, PA HTN (systolic &gt; 60 mm Hg), porcelain aorta, right ventricular failure, or history of mediastinal radiation therapy.</td>
</tr>
<tr>
<td>“High” Risk</td>
<td>&gt; 15% risk of 30 day mortality (Guideline STS and STS Plus &gt; 15%)</td>
<td>&gt; 15% risk of 30 day (Guideline STS PROM &gt; 10%)</td>
<td></td>
</tr>
</tbody>
</table>
There is an extraordinarily high incidence of stroke after cannulation and clamping of a severe atherosclerotic ascending aorta, with nine (45%) cerebrovascular accidents and four fatal strokes in a series of 20 pts.


Herrmann et al Ann Thorac Surg 2009:998
Beyond Frailty → Need for an Better Index

Frailty
Impairment in multiple systems that leads to a decline in homeostatic reserve and resiliency

Disability:
ADL
IADLs
Difficulty or dependency in daily living

Charlson
Co-Morbidities
Two or more medical conditions
Frailty is not represented in any of the commonly used risk scores.

STS has begun collecting 5-meter gait speed as a measure of frailty.

EuroSCORE II has added “Poor mobility” defined as severe impairment of mobility secondary to musculoskeletal or neurological dysfunction.
Frailty In AVR: STS Plus Incremental Risk

- Survey 40 Cardiac Surgeon
- Factors not Included in STS

- Perception is that Frailty Markers have an increased impact with age
### “STS Plus” Risks Determined by 40 Cardiac Surgeons

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>∆ Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>BNP ≥ 550 pg/mL</td>
<td>3%</td>
</tr>
<tr>
<td>NT ProBNP ≥ 3200 pg/mL</td>
<td>3%</td>
</tr>
<tr>
<td>Prohibitive Chest Deformity</td>
<td>5%</td>
</tr>
<tr>
<td>Hostile Mediastinum</td>
<td>15%</td>
</tr>
<tr>
<td>Prior Stroke / TIA</td>
<td>3%</td>
</tr>
<tr>
<td>FEV1 &lt; 750</td>
<td>20%</td>
</tr>
<tr>
<td>FEV2 750-1000 cc</td>
<td>5%</td>
</tr>
<tr>
<td>Home (Supplemental) O2</td>
<td>5%</td>
</tr>
<tr>
<td>Nocturnal BiPAP</td>
<td>2%</td>
</tr>
<tr>
<td>Severe Diastolic Dysfunction</td>
<td>4%</td>
</tr>
<tr>
<td>Liver Disease</td>
<td></td>
</tr>
<tr>
<td>Childs A</td>
<td>5%</td>
</tr>
<tr>
<td>Childs B</td>
<td>7%</td>
</tr>
<tr>
<td>Childs C</td>
<td>25%</td>
</tr>
<tr>
<td>Pulmonary Hypertension</td>
<td></td>
</tr>
<tr>
<td>60-80 mmHg</td>
<td>5</td>
</tr>
<tr>
<td>&gt; 80 mmHg</td>
<td>15%</td>
</tr>
<tr>
<td>Porcelain Aorta</td>
<td>20%</td>
</tr>
<tr>
<td>Age &gt; 85 and Prior CABG</td>
<td>3%</td>
</tr>
<tr>
<td>Severe Aortic Calcification</td>
<td>3%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Frailty Assessments</th>
<th>&lt; 80 Yrs</th>
<th>80-90 Years</th>
<th>&gt; 90 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI &lt; 21</td>
<td>4%</td>
<td>5%</td>
<td>6%</td>
</tr>
<tr>
<td>Albumin &lt; 3.3</td>
<td>4%</td>
<td>5%</td>
<td>7%</td>
</tr>
<tr>
<td>Wheelchair Bound</td>
<td>7%</td>
<td>8%</td>
<td>10%</td>
</tr>
<tr>
<td>Does Not Live Independently</td>
<td>5%</td>
<td>6%</td>
<td>9%</td>
</tr>
</tbody>
</table>
Interaction of Frailty and Pulmonary Disease

CLINICAL RESEARCH STUDY

Frailty and Respiratory Impairment in Older Persons

Carlos A. Vaz Fragoso, MD, Paul L. Enright, MD, Gail McAvay, PhD, Peter H. Van Ness, PhD, MPH, Thomas M. Gill, MD

*Yale University School of Medicine, Department of Internal Medicine, New Haven, Conn; †Clinical Epidemiology Research Center, VA Connecticut, West Haven; ‡University of Arizona, College of Public Health, Tucson.

- Slow gait speed—slowest quintile during a timed 15-feet walk (sex- and height-adjusted);
- Low physical activity—lowest quintile of kilocalories/week (sex-adjusted);
- Exhaustion—2 questions from the Center for Epidemiologic Studies–Depression Scale;
- Reduced grip strength—lowest quintile of the average of 3 dynamometer readings (sex and BMI adjusted); and
- Unintentional weight loss—at least 10 pounds in the prior year.
Interaction of Frailty and Pulmonary Disease

Figure 1  Adjusted hazard ratios (95% CI) for all-cause mortality, according to baseline frailty status and respiratory impairment (N = 3471). Single Cox regression model, adjusted for age, height, gender, smoking history, BMI, BMI², health status, and chronic conditions. The reference group included non-frail participants who had normal pulmonary function. There was a significant interaction between frailty and respiratory impairment (P = .037). Sample size of each subgroup is provided in Table 5.
The **CoreValve Frailty Index** includes measures of nutritional assessment, strength and balance, energy level, average daily living, mental status, and medical co-morbidities. The measures will be collected prospectively to assess the patients overall frailty for this study.

**Nutritional Assessment**
- Serum Albumin \(\leq 3.3 \text{ g/dL}\)
- Hematocrit \(\leq 35\%\)
- BMI (< 19)
- Unintentional Weight Loss

**Average Daily Living**
- Bathing, Dressing, Toileting, Transferring, Continence, Feeding

**Strength and Balance**
- Wheelchair-requirement \((0 = \text{No}; 1 = \text{Yes})\)
- Grip strength adjusted for weight-BMI (kgs)
- 15-foot walk test \((\text{m/s})\) (Get-Up and Go)
- Falls \((\geq 1 \text{ in past 6 mos})\)
- Assisted Living Center

**Energy Level**
- SF-36, Kansas City Cardiomyopathy Questionnaire

**Dementia**
- MMSE (0-30 points)
What Have Cardiologists Learned From Surgeons?

- TAVR Fundamentals
- “Multidisciplinary teams” and collaborations
- STS PROM is limited as a calibrated index for outcome in elderly patients with “High Risk” AS
  → “Extreme Risk” and “STS Plus”
- The Aortoartvalvular Complex
  → Residual Paravalvular Regurgitation, PPM
- Hybrid ORs: A necessity not extravagance
- Alternative Access Routes
  → Making Interventionalist think like surgeons
Diseased aortic valve leaflets in close proximity to…

- aortic root (annulus)
- coronary ostia
- sinuses of Valsalva
- anterior mitral leaflet
- membranous septum (AVN)
- LV outflow tract
The TAVR Landing Zone

SAPIEN
Length 16-17 mm

CoreValve
Length 53-55 mm

From TransCatheter Aortic Valve Implantation Serruys et al
Aorto Mitral Curtain $\rightarrow$ Anterior Mitral Valve Leaflet
Multimodality Imaging in Transcatheter Aortic Valve Implantation and Post-Procedural Aortic Regurgitation

Comparison Among Cardiovascular Magnetic Resonance, Cardiac Computed Tomography, and Echocardiography

Which Gold Standard for Annular Sizing?
N=202

Jabbour JACC 2011; 58:2143–50
Identifying the Basal Annular Plane

Perimeter 76.7 mm

LC Sinus
RC Sinus
NCC Sinus

RC 32.1
NC 35.7
LC 35.9
CoreValve Annular Sizing

<table>
<thead>
<tr>
<th>Valve Size</th>
<th>23</th>
<th>26</th>
<th>29</th>
<th>31</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annular Perimeter</td>
<td>63.5</td>
<td>68.4</td>
<td>78.5</td>
<td>87.3</td>
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<tr>
<td>Valve Perimeter</td>
<td>72.2</td>
<td>81.6</td>
<td>91.1</td>
<td>97.3</td>
</tr>
<tr>
<td>% Oversize</td>
<td>12%</td>
<td>16%</td>
<td>14%</td>
<td>10%</td>
</tr>
</tbody>
</table>
Severe calcification limited full circular expansion of the prosthesis

Litzler et al J Thorac Cardiovasc Surg 2008 136 697-701
PARTNER A

2 Year FU

No difference between sAV and TAVR for 2 year mortality

Kodali Partner A NEJM, April 26, 2012
What Have Cardiologists Learned From Surgeons?

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Unanticipated Iliac Rupture
Iliofemoral CT Angiogram

Tortuosity, Calcium, Marginal CSA

< OD 18Fr
6.93 mm
• TAVR Fundamentals
• “Multidisciplinary teams” and collaborations
• STS PROM is limited as a calibrated index for outcome in elderly patients with “High Risk” AS
  → “Extreme Risk” and “STS Plus”
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• Alternative Access Routes
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83 year old man
NYHA Class III
Porcelain Aorta
Annular Size 27.4 mm
Unsuitable iliofemoral access
Operative Plan:
RFA for 6 Fr Pigtail
Temporary Pacemaker FRV
Median Hemisternotomy
31 mm CoreValve
### Direct Aortic Access Approaches

<table>
<thead>
<tr>
<th>Incision Location</th>
<th>Sternotomy</th>
<th>Upper Sternotomy</th>
<th>Thoracotom</th>
<th>Port Access?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incision Size</strong></td>
<td>12+ cm</td>
<td>5+ cm</td>
<td>4-5 cm</td>
<td>1 cm</td>
</tr>
<tr>
<td><strong>Visualization</strong></td>
<td>Direct</td>
<td>Direct</td>
<td>Direct</td>
<td>Indirect</td>
</tr>
</tbody>
</table>
Direct Aortic – Median Hemisternotomy

Marker Clip
Direct Aortic – Median Hemisternotomy
Direct Aortic – Median Hemisternotomy
Direct Aortic – Median Hemisternotomy
Direct Aortic – Median Hemisternotomy

Overnight CV-ICU

Ambulating Next Day

Home on POD #4
TAVR is truly transformational technology for suitable patients with life-threatening aortic stenosis who are no ideal candidates for sAVR.

The impact of TAVR on both quality and quantity of life is profound, but it comes at a costs and is not free of substantial potential complications.

TAVR is not for every patient, particularly those with mortal co-morbidities.

Expanding to intermediate risk patients will require randomized clinical studies.

From a personal perspective, TAVR has facilitated multidisciplinary teams to develop therapy pathways that allow the treatment of a broader pool of patients.