Transcatheter Aortic Valve Replacement (TAVR)
Providence Heart and Vascular Institute
Eric Kirker MD FACS, ABTS
Providence Valve Center
Co-Surgical Director
October 20, 2012

Seldinger Technique
- Dr. Sven-Ivar Seldinger (1921-1998)
- Swedish Radiologist
- Introduced Technique in 1953

Structural Heart Therapy
- Surgery Based Techniques
  - Live real time direct visualization
  - Hands-on corrective therapy
- Imaging Based Techniques
  - Live real time indirect visualization
  - Tool based corrective therapy
- Hybrid Suite Concept
- “Hybrid” Physician-surgical and interventional skills
- Multidisciplinary TEAM
Structural Heart History
Balloons, Stents, Valves

• Vascular Disease
  – PTA, thrombolysis, stents, embolization
  – Coronary Stents
  – Aortic Stent Grafts
  – Carotid Stents
• Congenital Heart Disease
  – Transseptal Left Heart
  – Balloon Atrial Septostomy
  – Coarctation of Aorta
  – Pulmonary Artery Stenosis
  – ASD, VSD

• Valvular Disease
  – Valvuloplasty, BAV, MVP, PVP
  – Pulmonic Valve
    • Medtronic Melody® (2010)
  – Aortic Valve
    • Edwards SAPIEN®, RetroFlex3™ (2011)
    • Edwards SAPIEN XT®
    • Medtronic CoreValve®
    • St. Jude Medical Portico™
  – Mitral Valve
    • Abbott MitraClip® System

Multiple Technologies

• Edwards Sapien
  – Commercial
  – Inoperable patients
  – Femoral only (for now)
• Edwards Sapien XT
  – Lower profile
  – In context of Partner II study
    • Apical, transaortic, valve-in-valve
• E-Valve
  – Percutaneous mitral clip for severe MR
  – Coapt Mitrigrip study
  – Available at Providence Valve Center

• Medtronic Corevalve
  – Investigational – available at Providence Sacred Heart, Spokane, WA
  – Self-expanding
  – Providence Valve Center has referred 4 patients
Prevalence of Aortic Stenosis

- Aortic stenosis is estimated to be prevalent in up to 7% of the population over the age of 65.
- It is more likely to affect men than women; 80% of adults with symptomatic aortic stenosis are male.

Aortic Stenosis

Aortic stenosis refers to a narrowing of the aortic valve, which can lead to reduced blood flow from the heart to the body. This condition is more common in older adults and can result in symptoms such as chest pain, shortness of breath, and fatigue. Treatment options may include medication, lifestyle changes, and, in some cases, surgical intervention.
Aortic Stenosis Subtypes

- **Congenital** - before 6th decade
  - Bicuspid (1-2%), associated coarctation
  - Unicuspid (0.02%), infants, rarely adults
- **Rheumatic** - always associated with MV disease
  - Inflammatory
  - Commissure fusion
- **Calcific, Senile** - after 6th decade
  - No Fusion
  - Calcification
  - Atherosclerotic

Aortic Stenosis Symptom Triad

- Angina
- Dyspnea
- Syncope
  - All associated with exertion

Aortic Stenosis Physical Findings

- Murmur - crescendo, decrescendo
- Upper sternal border
- Radiates to carotids
- Delayed carotid pulse
- Diminished A2
- S4
Aortic Stenosis
Physiology/Compensatory Mechanisms

- Pressure overload
- Compensatory hypertrophy
- Diminished coronary blood flow reserve
- Increased LV diastolic pressure
- Increased pulmonary pressure
- Subendocardial ischemia
- LV enlargement and systolic failure

Aortic Stenosis is Life Threatening

Survival after onset of symptoms is 50% at two years and 20% at five years.
"Surgical intervention for severe AS should be performed promptly once even minor symptoms occur."

Valve Gradient

<table>
<thead>
<tr>
<th>Gradient (mmHg)</th>
<th>Area (cm²)</th>
<th>CO (L/min)</th>
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<tbody>
<tr>
<td>2</td>
<td>3.0</td>
<td>5.0</td>
</tr>
<tr>
<td>11</td>
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<td>1.25</td>
<td>5.0</td>
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<td>70</td>
<td>0.6</td>
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<tr>
<td>100</td>
<td>0.5</td>
<td>5.0</td>
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</table>
Addressing a Serious Unmet Need

- Studies show at least 40% of SAS patients are not treated with an AVR.

Aortic Valve Replacement Greatly Improves Survival

Sobering Perspective

5-year survival of breast cancer, lung cancer, colorectal cancer, ovarian cancer and severe inoperable aortic stenosis.
ASE Guidelines
ECHO is Gold Standard

<table>
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<tr>
<th>Recommendations for classification of AS severity</th>
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<tr>
<td>Valve area (cm²)</td>
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<tr>
<td>Jet width, mm</td>
</tr>
<tr>
<td>Ejection fraction</td>
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</table>

Providence Valve Center June 1, 2011

- Options for Aortic Stenosis Patients
- Transcatheter Valve Technology
- Required Multidisciplinary Evaluation
- Continued Growth of PHVI
- Research Potential
- Stature in Valve Disease Therapies
- Other Valve Therapies

Transcatheter Aortic Valve Implantation/Replacement
(TAVI/TAVR)

- First available in 2002 (Alain Cribier)
- Rapid growth throughout the world for the treatment of severe AS in patients who are at high surgical risk (~ 40,000)
- “Additional” ~ 25% of cases in Germany
- 2007-2009 Placement of AoRTic TraNscathetER Valve Trial (PARTNER TRIAL)
- November 2, 2011 FDA approval of Edwards SAPIEN® with the RetroFlex3™(21-24Fr) for commercial release
PARTNER Study Sites

- Intermountain Medical Center
  - Salt Lake City, UT
- Emory University
  - Atlanta, GA
- Univ. of Miami
  - Miami, FL
- Univ. of Virginia
  - Charlottesville, VA
- St. Luke’s Hospital
  - Kansas City, MO
- Barnes-Jewish Hospital
  - St. Louis, MO
- Medical City Dallas
  - Dallas, TX
- St. Paul’s Hospital
  - Vancouver, Canada
- Univ. of Washington
  - Seattle, WA
- Mayo Clinic
  - Rochester, MN
- Stanford University
  - Palo Alto, CA
- Hospital Laval
  - Quebec City, Canada
- Ochsner Foundation
  - New Orleans, LA
- Scripps Clinic
  - La Jolla, CA
- Cedars-Sinai Medical Center
  - Los Angeles, CA
- Cleveland Clinic
  - Cleveland, OH
- Columbia University
  - Cornell University
  - New York, NY
- Washington Hosp. Center
  - Wash., DC
- Univ. of Penn
  - Phila., PA
- Brigham & Women’s
  - Mass General
  - Boston, MA
- Northwestern Univ.
  - Chicago, IL
- Toronto Gen. Hospital
  - Toronto, Canada
- Evanston Hospital
  - Leipzig Heart Center
  - Leipzig, Germany

n = 1,057 patients
26 investigator sites
22 USA, 3 Canada, 1 Germany

TAVR Program Overview

• First TAVR in Oregon
  – February 1st, 2012
• First Oregon PARTNER II TAVR-TF
  – April 5th, 2012
• First Oregon PARTNER II TAVR-TA
  – August 21st, 2012
• Excellent multidisciplinary collaboration
  of multiple physicians, staff (eg. Echo, peripheralist, anesthesia, etc)

Providence Valve Center
An Integrated Approach
Providence Valve Center
Multidisciplinary Team

- Interventional Cardiology
  - Caulfield, Hodson, Korngold
- Cardiac Imaging
  - Walsh, Rahimtoola, Wilson
  - Zinck, Warfel
- Cardiac Surgery
  - Swanson, Kirker
- CV Anesthesia
  - Kelly
- Nurse Coordinator
  - Marla Craft
- Administrative Assistant
  - Kristina Wilson

Quarterly Referrals to Providence Valve Center

<table>
<thead>
<tr>
<th>Referrals to Providence Valve Center</th>
<th>2011Q1</th>
<th>2011Q2</th>
<th>2011Q3</th>
<th>2011Q4</th>
<th>2012Q1</th>
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Providence Valve Center Quarterly Case Totals

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<th>Providence Valve Center Case Totals</th>
<th>2011Q1</th>
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<td>36</td>
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Providence Valve Center
Experience To Date  September 2012

- TAVR - 20 (23 through October)
  - Commercial - 7
  - PARTNER II - 13
  - TF - 9
  - TA - 4
- SAVR - 42
  - PARTNER II - 6
  - PH&S - 36
- Referred to CoreValve in Spokane: 4
  - Treated - 1
- Referred to other centers: 3 (IMHC, Swedish)

*As of July 2012

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**Valve Surgeries, July 2010 - June 2012**

<table>
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<tr>
<th>Year</th>
<th>PVC Opens</th>
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**PARTNER Study Design**

**Symptomatic Severe Aortic Stenosis**

- n= 700
- High Risk
- n= 358
- Inoperable

- Total = 1058 patients
- 2 Parallel Trials: Individually Powered

---

Data Source: PATS STS Adult Cardiac Surgery Registry, S.Fine, RHVDS 7-2-12

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GENERAL CLINICAL INDICATIONS FOR TAVR

- Age > 75
- Severe and symptomatic aortic stenosis
- Moderate to high surgical risk
  - PARTNER I and Commercial, STS >10%
  - PARTNER II, STS >4%
- Exceptions
  - Porcelain Aorta
  - Hostile Chest
  - Severe Pulmonary Disease
  - Midline LIMA/RIMA
  - Frailty
  - Severe Pulmonary Hypertension
  - Dementia
  - Cirrhosis
  - Severe Cerebral Vascular Disease

PARTNER Patient Population

- Severe symptomatic aortic stenosis
  - AVA of < 0.8 cm²
  - Either mean AV gradient of > 40 mm Hg
  - Or peak aortic-jet velocity of > 4.0 m/sec
- All the patients had NYHA class II, III, or IV symptoms

All Cause Mortality (ITT)
Crossover Patients Followed

- Standard Rx
- NNT = 3.0 pts
- P (log rank) < 0.001
- Δ at 1 yr = 30.1%
- Δ at 2 yr = 24.3%
- NNT = 4.1 pts

<table>
<thead>
<tr>
<th>Month</th>
<th>Count (Standard Rx)</th>
<th>Count (ITT)</th>
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<td>12</td>
</tr>
<tr>
<td>54</td>
<td>12</td>
<td>12</td>
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Cohort B
Cohort B Down Side at 1 year

TAVI vs Control

- All Stroke/TIA: 10.6 vs 4.5%
- Vascular Complications:
  - All: 32.4 vs 7.3%
  - Major: 16.8 vs 2.2%
  - Major bleeding: 22.3 vs 11.2%

All-Cause Mortality (ITT)

Published Cost Effectiveness Estimates
Case Study
• 83 yo female rancher, Eastern OR
• Persistent AF (on dabigatran)
• CRI, eGFR 56 ml/min, Cr 0.95
• Moderate to severe TR
• Referred to CV surgeon by PCP for surgery eval for severe AS

GENERAL NON-INDICATIONS FOR TAVR
• Age < 70
• Refusal of surgery
• Life expectancy < 1 yr

CLINICAL DECISION PROCESS
• Confirm Severe AS
• Symptomatic
• Risk Assessment
• Technical feasibility
TAVR WORK UP

- Calculate risk scores
- Frailty Assessment
- TTE or TEE – TEE routine part of procedure
- CTA chest, abdomen, pelvis – “TAVR protocol”
  - Gated
  - Beta-blockade issues
  - Contrast issues
- Coronary angiography, right heart cath
- PFTs, pulmonary consult
- Carotid US

COMMENTS
- If any “NO” then consider Multidisciplinary Consult (MC) first.
- If patient is likely SAVR, consider RHC/Cor first then MC before CTA or refer to surgeon.
- If patient likely TAVR or P2, do RHC/Cor and CTA before MC.
- All have an accurate STS.
- All have a MC.
- All are reviewed at Multidisciplinary Conference.
- 9/5/2012

PVC- Facilitated TAVR Work-up

<table>
<thead>
<tr>
<th>Clinical Exam? NYHA II?</th>
<th>Qualifying Echo or DSE?</th>
<th>STS&gt;4%?</th>
<th>All Yes</th>
<th>Order work up</th>
<th>Multidisciplinary Consult</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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All have an accurate STS.
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9/5/2012

Online STS Risk Calculator

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Calculation</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

- MVA (mitral valve area) = 0.626 x Body surface area x 3.735
- Arch area = 0.8 x Body surface area
- LVEDD (left ventricular end diastolic dimension) = 0.4 x Body surface area
- LVESD (left ventricular end systolic dimension) = 0.4 x Body surface area
- EF (ejection fraction) = 0.4 x Body surface area
- RV (right ventricular) = 0.4 x Body surface area
- Aortic valve area = 0.626 x Body surface area
- Aortic regurgitation = 0.626 x Body surface area
- Mitral regurgitation = 0.626 x Body surface area
- Tricuspid regurgitation = 0.626 x Body surface area
- Pulmonary hypertension = 0.626 x Body surface area
- Hypertension = 0.626 x Body surface area
- Diabetes = 0.626 x Body surface area
- Age > 70 = 0.626 x Body surface area

- New SNF = 2
- New Medicare = 2
- New CPT = 2
- New ICD = 2
- New IMR = 2
- New RVF = 2
- New LVEF = 2
- New Glucose = 2
- New BP = 2
- New Cholesterol = 2
- New Weight = 2
- New CVD = 2
- New Depression = 2
- New COPD = 2
- New Asthma = 2
- New CHF = 2
- New Cancer = 2
- New Renal = 2
- New PVD = 2
- New Alcohol = 2
- New Smoking = 2
- New GI = 2
- New Sleep = 2
- New Thyroid = 2
- New Vision = 2
- New Neuropathy = 2
- New Skin = 2
- New Other = 2

Revised Date: 12/12/2014
RN Clinic Assessment

- Frailty Assessment
  - 15 foot timed walk test
  - Grip Strength
  - ADL score
  - Albumin
- Mental Function
  - MMSE: mini mental status exam
- Patient and Family motivation and expectations
- Quality of Life
- Social Support
- Decision Making Support
LVOT 2.01 cm
Annulus 2.22 cm

Potential Recommendations:
- Routine Valve Surgical Valve Replacement
  - Aortic
  - Mitral, tricuspid
- Percutaneous Valve Replacement
  - Edwards Sapien (Aortic)
  - Evolve MitraClip (Mitral)
- Continued Medical Therapy
  - Consider balloon valvuloplasty
  - Consider Connections consult
  - Continued Observation

CM 1/27/17
CATH
3/12/12
RA 10
PA 44/19/31
PCWP 16
CO/CI 3.17/1.71 (TD)
2.62/1.41 (est Fick)
Attention to detail

TIMEOUTS 1,2,3

- JCAHO Timeout?
- System rebooted?
- Defibrillator
- Conversion checklist
- CPB plan
  - Commercial: pt wishes (y/n)
  - Femoral vs. chest
- Valvuloplasty balloon
- Pacer capture
- Particular concerns
  - Renal failure
  - CAD
  - Echo findings
  - Arrhythmia
  - Peripheral access
- If transfemoral:
  - Sheath sewn in?
  - Aortic occlusion balloon
- Valve propped/checked
- Valve positioning plan
Trans-apical Approach

Post Operative Care

- #1 ....this is an AVR!
- Potential Complications
  - Vascular Access complications
  - Stroke
  - AV block
  - Acute MI
  - Acute Renal failure

TAVR patient with aortic stenosis

- Cognitive decline/ dementia
- Deconditioning
- Malnutrition
- CVA, PVD, CHF, COPD
- Lack of social support
- Depression
- Incontinence
- Alcohol dependence
- Osteoarthritis +/- joint replacement
- Renal insufficiency
- Inappropriate housing
- Balance problems/ immobility
- Chronic benzodiazepine use
- Living alone
- Polypharmacy
What I tell my patients

• Without surgery or TAVR ~50% mortality in 1-3 years
• Calculate and discuss STS score
• TAVI risks vary
  – 5-10% risk of dying in first 30 days
  – 20-30% risk of dying in one year
  – Most deaths after 30 days are non-cardiac
  – ~30% are pulmonary deaths
  – 10% risk of stroke in non-operative group
  – Stroke risk may be lower with surgery in high risk operable group (5.5% TAVI vs 2.4% AVR)
  – 20-30% major vascular/bleeding complications
• We don’t know how long these valves will last
  – 5 year experience looks good