


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


Structural Heart History 

Balloons, Stents, Valves

- 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 Mitraclip study
- Medtronic Corevalve
 - Investigational – available at Providence Sacred Heart, Spokane, WA
 - Self-expanding
 - Providence Valve Center has referred 4 patients



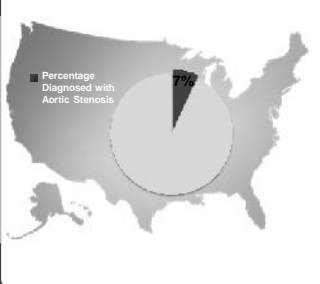
Available at Providence Valve Center

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Prevalence of Aortic Stenosis

- Aortic stenosis is estimated to be prevalent in up to 7% of the population over the age of 65¹
- It is more likely to affect men than women; 80% of adults with symptomatic aortic stenosis are male²

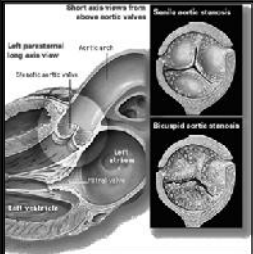
16.5 Million People in US Over the Age of 65²



Percentage Diagnosed with Aortic Stenosis

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Aortic Stenosis






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Aortic Stenosis

Normal	Rheumatic	Calcific	Bicuspid
			
			




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

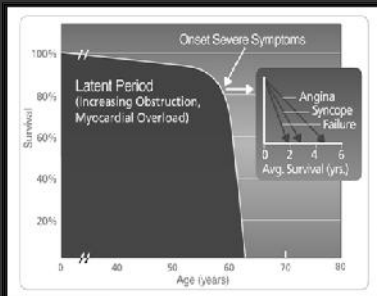


Physiology/Compensatory Mechanisms

- 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 LifeThreatening






Survival after onset of symptoms is 50% at two years and 20% at five years¹

"Surgical intervention [for severe AS] should be performed promptly once even...minor symptoms occur"²

S.J. Lubin et al., "The Natural History and Rate of Progression of Aortic Stenosis," *Chest* 1955.
 C.M. Otto, "Valve Disease: Timing of Aortic Valve Surgery," *Heart* 2007 Chart: Ross J.J., Braunwald E. *Aortic Stenosis*, Circulation 1996;98:Suppl 1:91-7.

Valve Gradient



Gradient (mmHg)	Area (cm ²)	CO (L/min)
2	3.0	5.0
11	2.5	5.0
16	1.25	5.0
25	1.0	5.0
45	0.75	5.0
70	0.6	5.0
100	0.5	5.0

↓
 20Yrs
↓
 5 Yrs

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Addressing a Serious Unmet Need

Year	No AVR (%)	AVR (%)
Edwards 1999	40	56
Pedibala 2005	57	43
Chambers 2006	48	52
Worachetwint 2007	35	65
Jain 2009	26	74
Etch 2009	48	52
Freed 2010	31	69

- Studies show at least 40% of SAS patients are not treated with an AVR⁹⁻¹⁵

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Aortic Valve Replacement Greatly Improves Survival

Years	AVR, no Sx	AVR, Sx	No AVR, no Sx	No AVR, Sx
0	100	100	100	100
1	95	90	95	50
2	92	85	90	35
3	90	80	85	25
4	88	75	80	20
5	85	70	75	18
6	82	65	70	15
7	80	60	65	12
8	78	55	60	10
9	75	50	55	8
10	72	45	50	7
11	70	42	45	6
12	68	40	42	5
13	65	38	40	4
14	62	35	38	3
15	60	32	35	2

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Sobering Perspective

Cancer Type	Survival %
Breast Cancer	23
Lung Cancer	4
Colorectal Cancer	12
Prostate Cancer	30
Ovarian Cancer	28
Severe Inoperable AS*	3

*Using constant hazard ratio. Data on file, Edwards Lifesciences LLC. Analysis courtesy of Murat Tuzcu, MD, Cleveland Clinic

5 year survival of breast cancer, lung cancer, prostate cancer, ovarian cancer and severe inoperable aortic stenosis

ASE Guidelines
ECHO is Gold Standard





Table 3 Recommendations for classification of AS severity

	Aortic sclerosis	Mild	Moderate	Severe
Aortic jet velocity (m/s)	<2.5 m/s	2.6-2.9	3.0-4.0	>4.0
Mean gradient (mmHg)	—	<20 (<30°)	20-40° (30-50°)	>40° (>50°)
AVA (cm ²)	—	>1.5	1.0-1.5	<1.0
Indexed AVA (cm ² /m ²)	—	>0.85	0.60-0.85	<0.6
Velocity ratio	—	>0.50	0.25-0.50	<0.25

*ESC Guidelines.
 †AHA/ACC Guidelines.



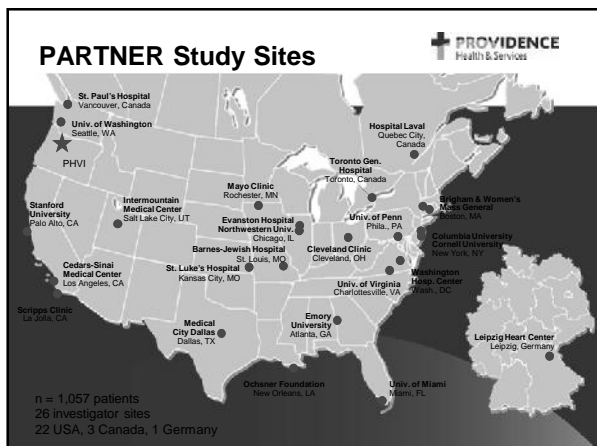
Providence Valve Center June 1, 2011

- 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



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)

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An Integrated Approach

Patient Screening Physician Partnership Procedural Training

High Quality Imaging Multidisciplinary Treatment

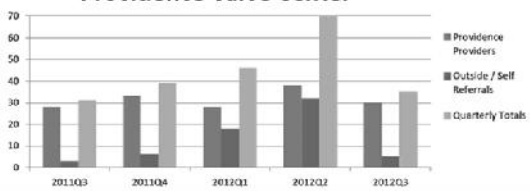
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Multidisciplinary Team

- 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

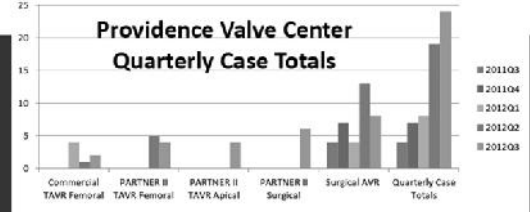


Quarterly Referrals to Providence Valve Center




Referrals to Prov Valve Center	2011Q3	2011Q4	2012Q1	2012Q2	2012Q3	Totals
Providence Providers	28	33	28	38	30	157
Outside / Self Referrals	3	6	18	32	5	64
Quarterly Totals	31	39	46	70	35	221

Providence Valve Center Quarterly Case Totals

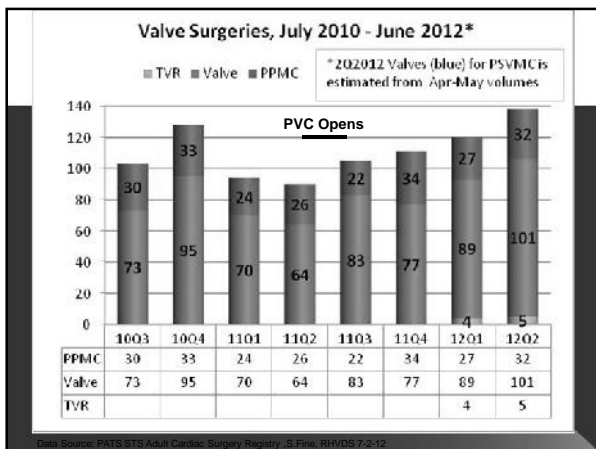


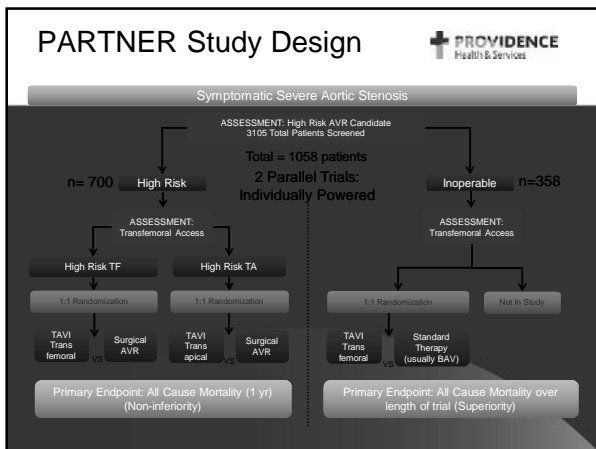
Providence Valve Center Cases	2011Q3	2011Q4	2012Q1	2012Q2	2012Q3	Total
Commercial TAVR Femoral	0	0	4	1	2	7
PARTNER II TAVR Femoral	0	0	0	5	4	9
PARTNER II TAVR Apical	0	0	0	0	4	4
PARTNER II Surgical	0	0	0	0	6	6
Surgical AVR	4	7	4	13	8	36
Quarterly Case Totals	4	7	8	19	24	62

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






GENERAL CLINICAL INDICATIONS FOR TAVR

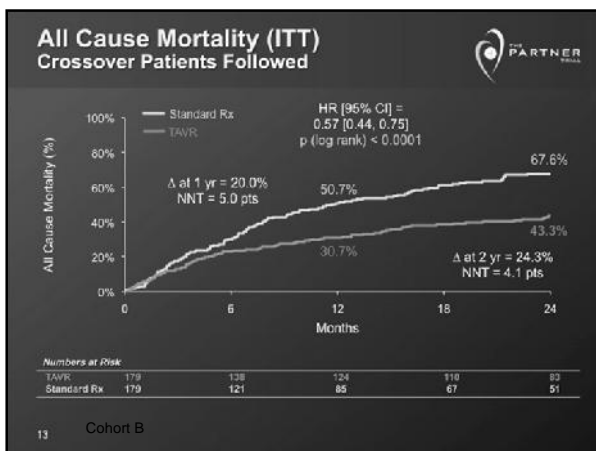


- Age \geq 75
- Severe and symptomatic aortic stenosis
- Moderate to high surgical risk
 - PARTNER I and Commercial, STS >10%
 - PARTNER II, STS >4%
- Exceptions
 - Porcelain Aorta
 - Hostile Chest
 - Severe Pulmonary Disease
 - Midline LIMA/RIMA
 - Frailty
 - Severe Pulmonary Hypertension
 - Dementia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

PARTNER Patient Population



- Severe symptomatic aortic stenosis
 - AVA of \leq 0.8 cm²
 - AND
 - 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

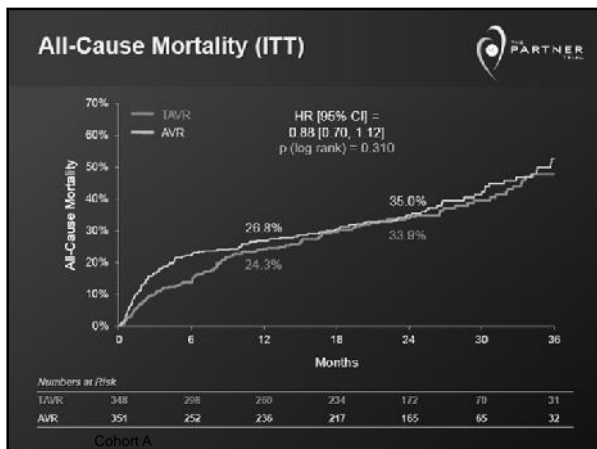


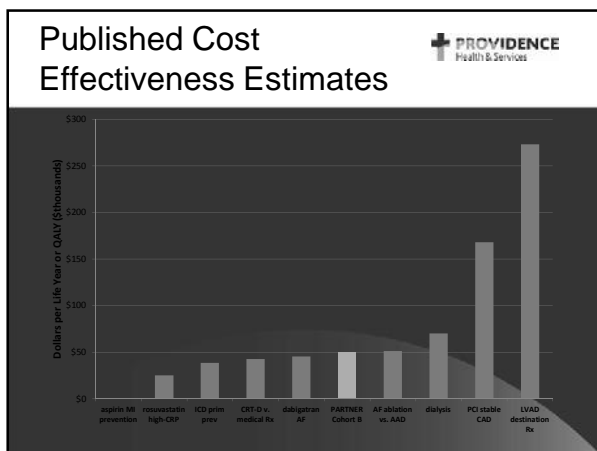
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Cohort B Down Side at 1 year

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%









Case Study


- 83 yo female rancher, Eastern OR
- Persistent AF (on dabagitrán)
- 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

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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 angio, right heart cath
- PFTs, pulmonary consult
- Carotid US

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PVC- Facilitated TAVR Work-up

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

Flowchart:

- Clinical Exam? NYHA II-IV?
 - Qualifying Echo or DSE?
 - STS>4%?
 - All Yes
 - Dictate Complete Consult
 - Order work up
 - Multidisciplinary Conference
 - Multidisciplinary Consult
 - CTA
 - RHC/Cor

Online STS Risk Calculator Database: 1.13 Definitions Support

Help [About this Calculator](#) New Print **Calculations**

Today's Date: 5/13/2012

Procedure Name: **Isolated AVR/Co**

Risk of Mortality: **8.543%**

Morbidity or Major Complication: **27.566%**

Long Length of Stay: **18.073%**

Short Length of Stay: **8.865%**

Permanent Stroke: **2.176%**

Prolonged Ventilation: **18.596%**

DSW Infection: **0.764%**

Renal Failure: **18.982%**

Reoperation: **18.042%**

Procedure:

Coronary Artery Bypass Yes No Missing

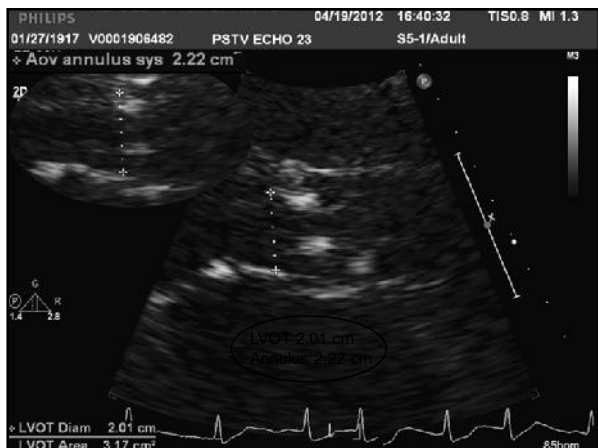
Valve Surgery Yes No Missing

Aortic Yes No Missing

Aortic Procedure




- Reassessment
- Root/Reconstruction
- Root Reconstruction with valved conduit
- Replacement and intaker aortic non-valved conduit
- Replacement Aortic Valve without replacement of ascending Aorta
- Replacement Aortic Valve with replacement of ascending Aorta
- Aortic aortic conduit (Aortic valve bypass)
- Coronary with pulmonary valve Ross procedure
- Hemigrraft
- Valve sparing root replacement (David)
- Valve sparing root remodeling (Yacoub)
- Other

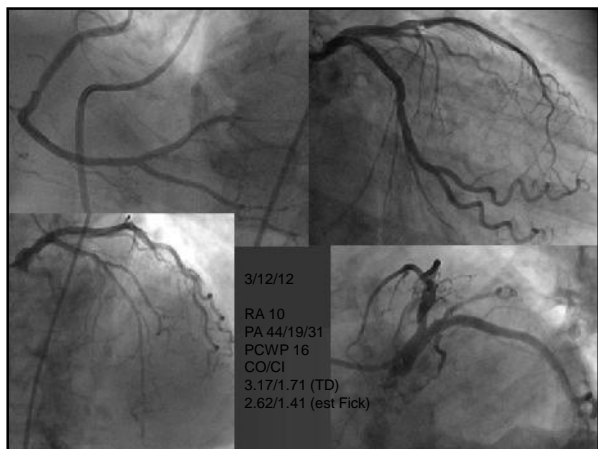
Reoperation of Sub-Aortic Stenosis Yes No Missing

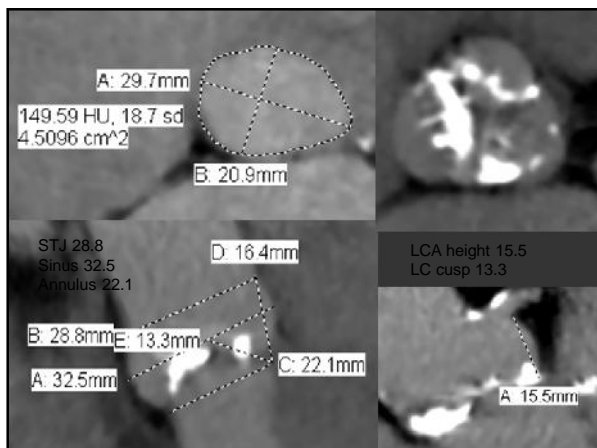


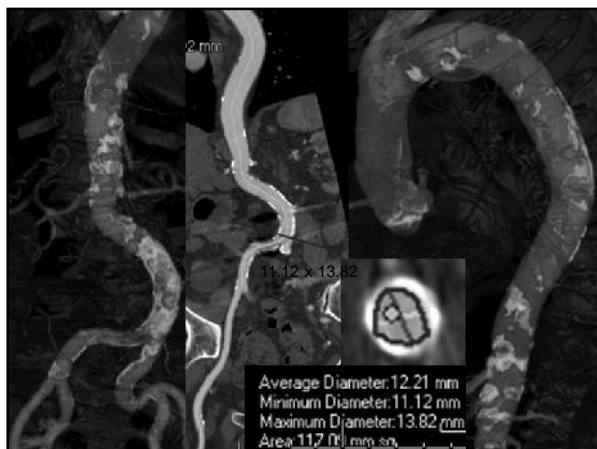
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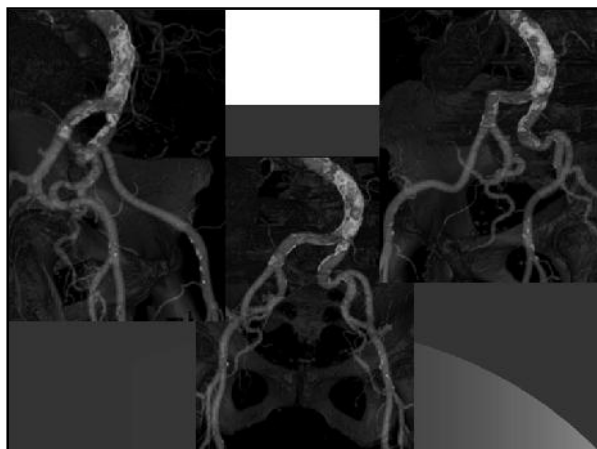
Potential Recommendations:

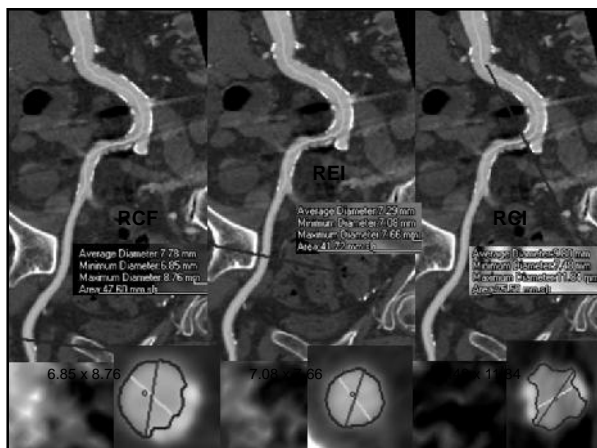
-  Routine Valve Surgical Valve Replacement
 - Aortic
 - Mitral, tricuspid
-  Percutaneous Valve Replacement
 - Edwards Sapien (Aortic)
 - Evalve Mitraclip (Mitral)
-  Continued Medical Therapy
 - Consider balloon valvuloplasty
 - Consider Connections consult
 - Continued Observation

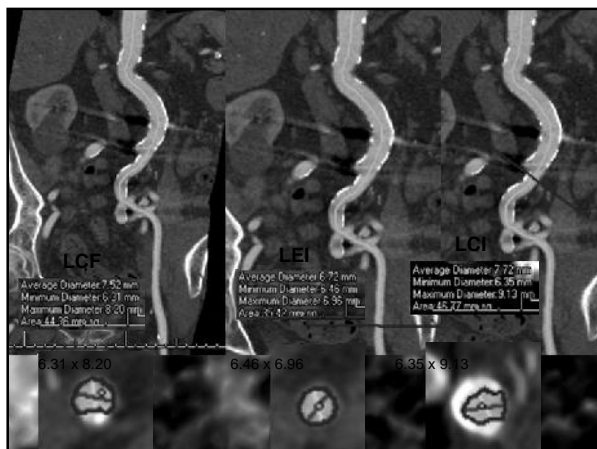








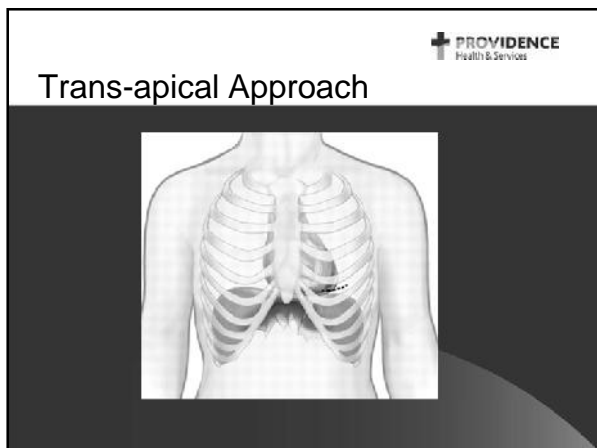


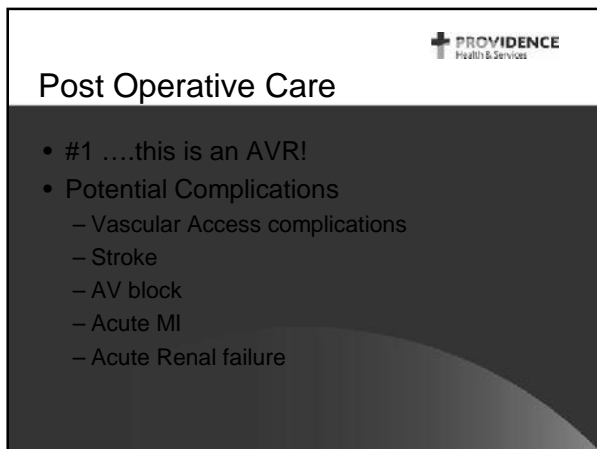


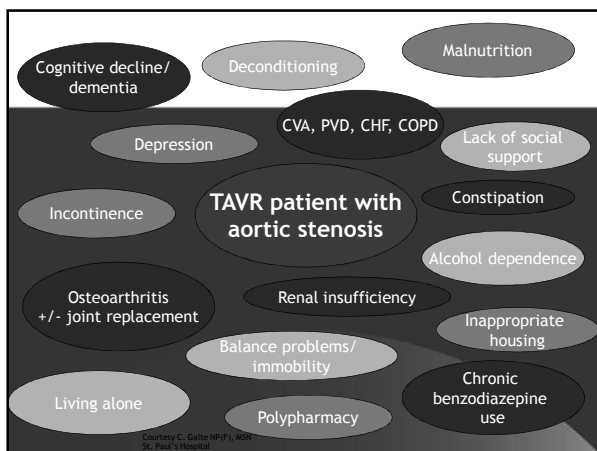
Attention to detail


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 prepped/checked
- Valve positioning plan











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-operable 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





Patient Referral - Providence Valve Center

Must be a patient of Providence St. Joseph Hospital

Providence St. Joseph Medical Center
3333 16th Avenue North
Portland, OR 97208
P: 503-254-2000
F: 503-254-0700
800-333-3333

Northwest Portland Medical Center
Aurora Center
Portland, OR 97207
P: 503-254-2000
F: 503-254-0700
800-333-3333

Date of Referral: _____ Patient Name: _____ DOB: _____ Ethnicity: _____
 M: _____ F: _____ MRSA (if applicable): _____ Referring Physician: _____
 Patient Reason: _____ (Please include if forward/echo/egderg. New/1 for _____)
 Patient Address: _____ (Please include if preferred to be signed for) P.O. # _____
 Alternate Contact Name: _____ Home _____

Consulting Physician:
 "Consulting Physician" Yes/No: _____ If yes, number to call: _____
 Referring Physician will see patient in Valve Center (in joint or established/elsewhere) Yes/No: _____
 If yes, date patient to be seen: _____

Appropriate In-Letter Referral Reason:

- all referrals are processed through the Providence Valve Center
- consults/requests made to appropriate cardiac subspecialties, CT chest and/or femoral artery, additional views and imaging, medical history of aortic disease
- Cases are referred to Providence Valve Center for consideration for aortic procedure. This includes:
 - o consideration of transcatheter aortic valve replacement (TAVI)
 - o aortic valve disease
 - o patient medical comorbidities
 - o emerging aortic disease/aneurysm, or aortic regurgitation

The patient, patient's family (if available) and referring physician will be notified of the best recommendations by a Providence Valve Center physician or nurse coordinator.

Preference for Follow up: _____ Patient Care _____ (the first contact only)

VERY IMPORTANT:
 Please send a copy of all relevant records, including:

| | |
|---|--|
| <input type="checkbox"/> Recent history | <input type="checkbox"/> Biopsy report |
| <input type="checkbox"/> Pulmonary evaluation | <input type="checkbox"/> ECG, EKG |
| <input type="checkbox"/> Pulmonary function tests | <input type="checkbox"/> CT Scan |
| <input type="checkbox"/> Radiology/fluoroscopy studies | <input type="checkbox"/> Cardiac Catheterization |
| <input type="checkbox"/> Hematology/oncology consultation | <input type="checkbox"/> Stress Test |
| <input type="checkbox"/> Cardiac/thoracic consultation | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Major blood work | |

Please indicate which records are New and which are Old

THANK YOU

valvecenter@providence.org
