


Transcatheter Aortic Valve Replacement (TAVR)


Providence Heart and Vascular Institute


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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



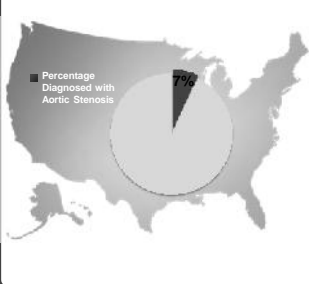
Available at Providence Valve Center

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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

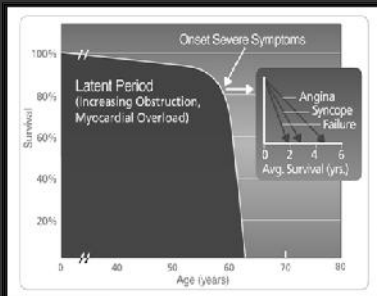


Physiology/Compensatory Mechanisms

- 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

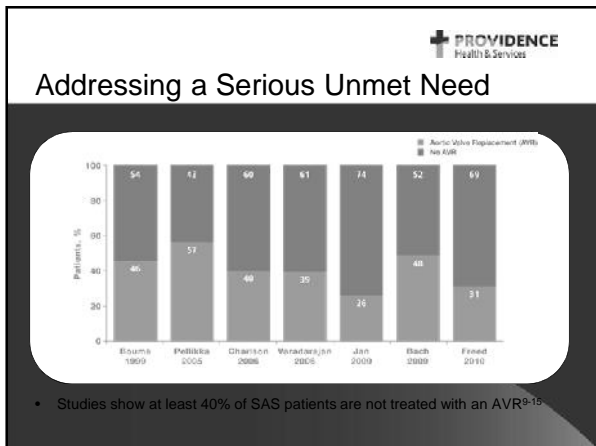
S.J. Lubin et al., "The Natural History and Rate of Progression of Aortic Stenosis," *Chest* 1993.
 C.M. Otto, "Valve Disease: Timing of Aortic Valve Surgery," *Heart* 2003; Ross J.J., Braunwald E. *Aortic Stenosis*, Circulation 1996; Braunwald E (1997).

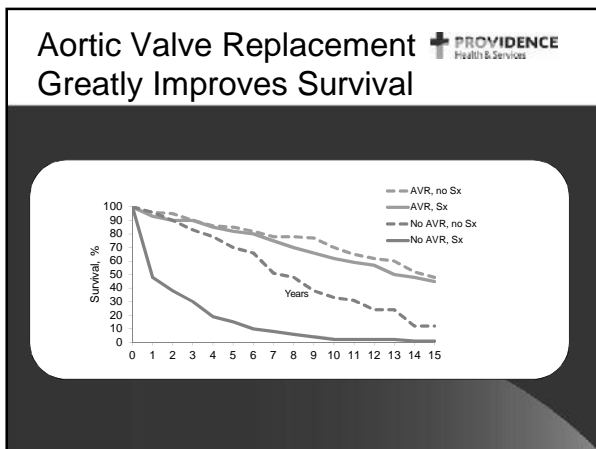
Valve Gradient

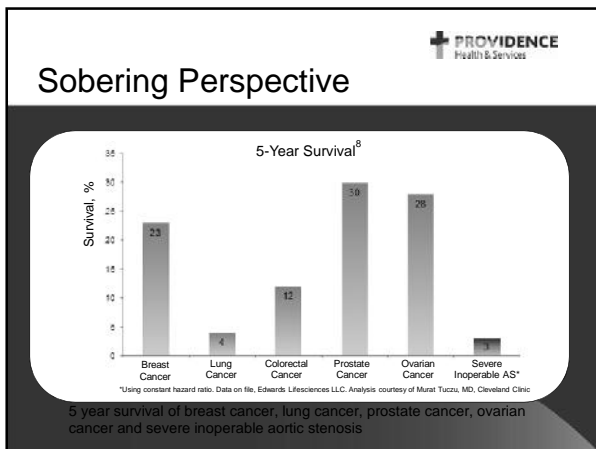


Gradient (mmHg)	Area (cm ²)	CO (L/min)
2	3.0	5.0
11	2.5	5.0
16	1.25	5.0
25	1.0	5.0
45	0.75	5.0
70	0.6	5.0
100	0.5	5.0

↓ 20Yrs
↓ 5 Yrs







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.



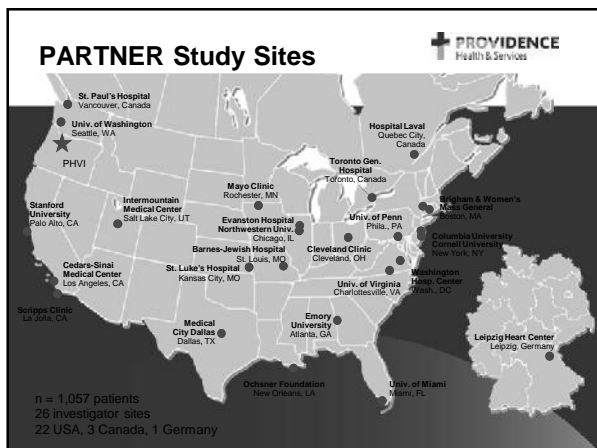
Providence Valve Center June 1, 2011

- 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

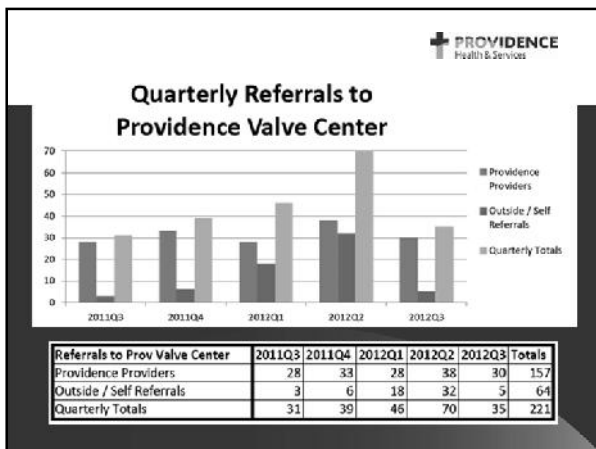
High Quality Imaging Multidisciplinary Treatment

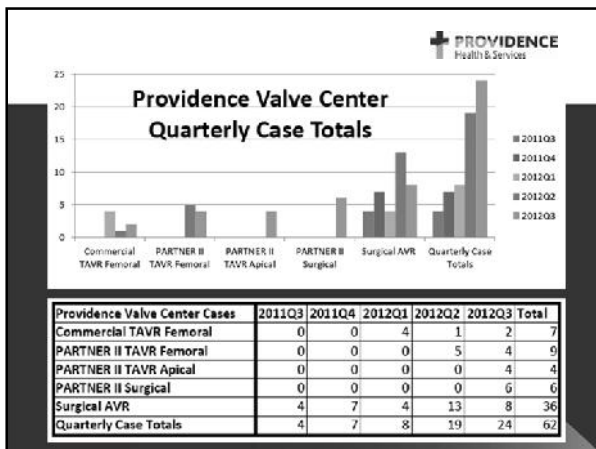
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Multidisciplinary Team

- 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



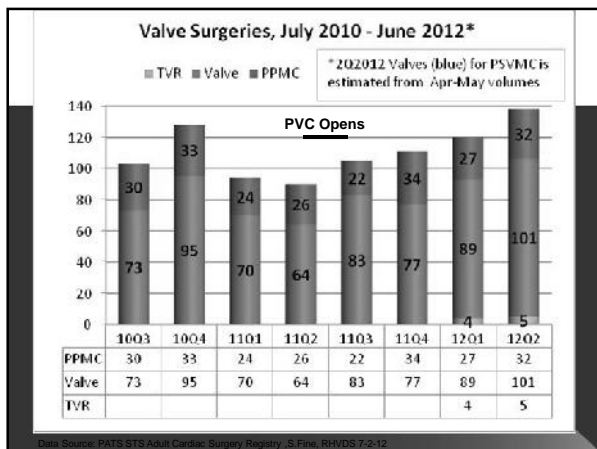


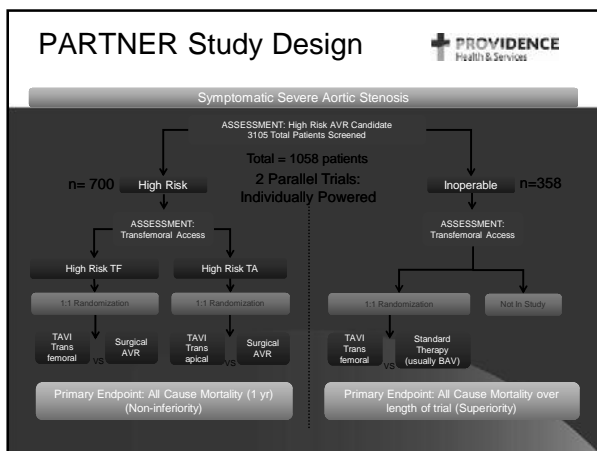


Providence Valve Center  **Experience To Date** September 2012


- 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

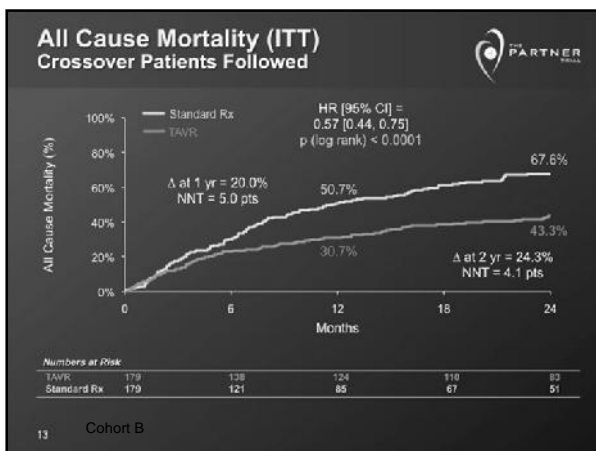


- Age \geq 75
- Severe and symptomatic aortic stenosis
- Moderate to high surgical risk
 - PARTNER I and Commercial, STS >10%
 - PARTNER II, STS >4%
- Exceptions
 - Porcelain Aorta
 - Hostile Chest
 - Severe Pulmonary Disease
 - Midline LIMA/RIMA
 - Frailty
 - Severe Pulmonary Hypertension
 - Dementia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

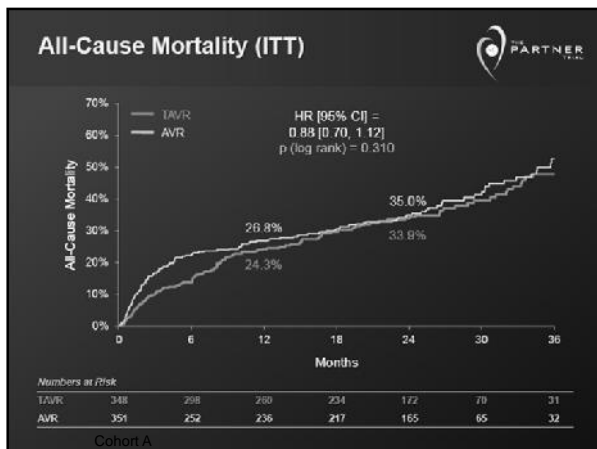


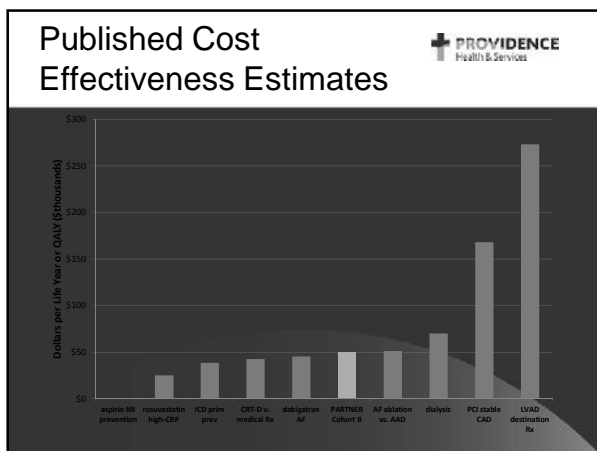
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Cohort B Down Side at 1 year

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
- Hemograft
- Valve sparing root resection (David)
- Valve sparing root resection (Yacoub)
- Other

Reoperation of Sub-Aortic Stenosis Yes No Missing




emSCORE: interactive calculator

important: The previous add-on¹ and legacy² EuroSCORE models are out of date. A new model has been prepared from fresh data and is launched at the 2011 EACTS meeting in Lisbon. The model is called EuroSCORE II. It is this online calculator that has been updated to use this new model. If you need to calculate the older 'add-on' or 'legacy' EuroSCORE please visit the old calculator for sickkids.net.


| Patient related factors | | Cardiac related factors | |
|--|---------------------------------|--|--|
| Age ³ (years) | 50 | N/A | N/A |
| Gender | male [8] | CCS class 4 angina ⁴ | no [8] |
| Peak impairment ⁴ due to aortic disease for maximum aortic regurgitation ⁵ | moderate (CC = 50 & aortic [8]) | LV function | good (WVF > 50%) [8] |
| Major aortic regurgitation ⁵ | no [8] | Recent MI ⁶ | no [8] |
| Previous cardiac surgery | no [8] | Pulmonary hypertension ¹⁰ | moderate (RA systolic 3.0-3.5 average [8]) |
| Chronic lung disease ⁷ | yes [8] | Urgency ¹¹ | elective [8] |
| Active endocarditis ⁸ | no [8] | Weight of the intervention ¹² | single non-CABG [8] |
| Critical preoperative status ⁹ | no [8] | Surgery on thoracic aorta | no [8] |
| Valvular aneurysm | no [8] | | |
| EuroSCORE II | 2.1 | | |
| EuroSCORE II | 2.1 | | |


Notes: This is the EuroSCORE II calculator.




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

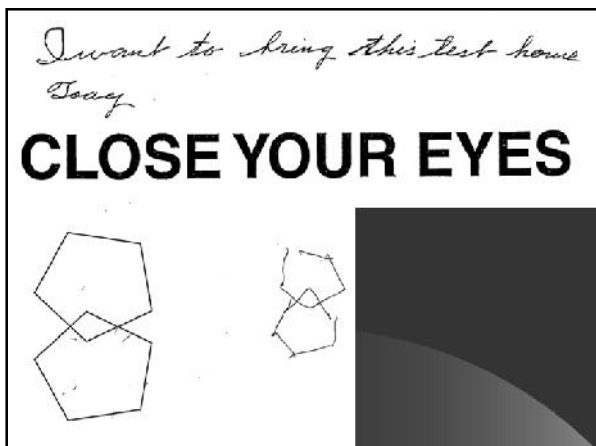




SOAP Note for patient S.V.N. Date: 10/25/12. Includes history, physical exam, assessment, and plan.



Assessment form with sections for history, physical, and assessment. Includes fields for symptoms, signs, and interventions.



TRIM Velocity Index Assessment

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Patient Name: _____
Exam Room: 517E11

Date of Birth: 1-17-19 Date Examined: 10/23/12

1. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

2. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

3. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

4. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

5. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

6. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

7. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

8. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

9. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

10. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

11. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

12. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

13. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

14. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

15. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

16. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

17. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

18. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

19. Area Definition of Body Limb

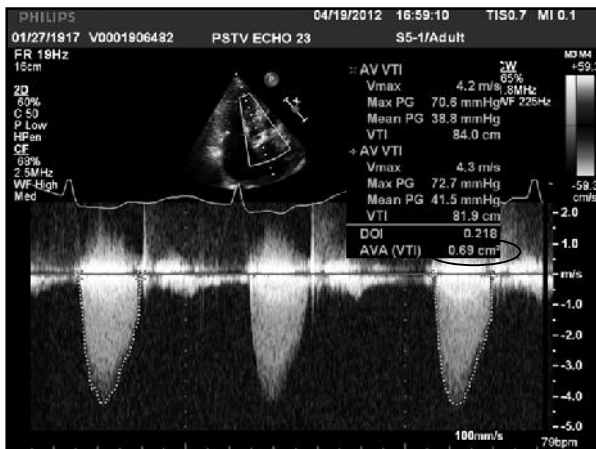
APPROXIMATE POINTS (100) _____

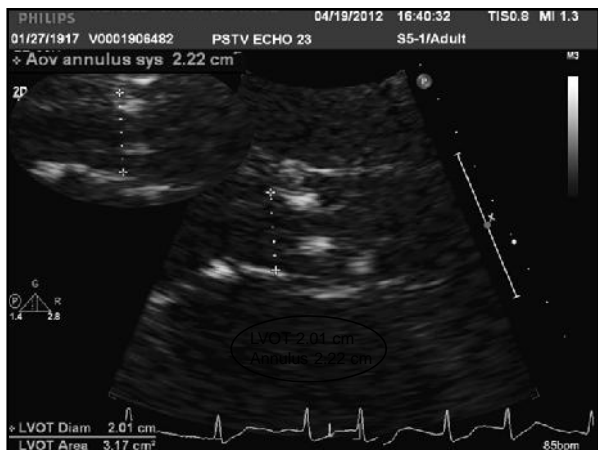
20. Area Definition of Body Limb

APPROXIMATE POINTS (100) _____

Considered by: Michelle Lopez




Page 2 of 3



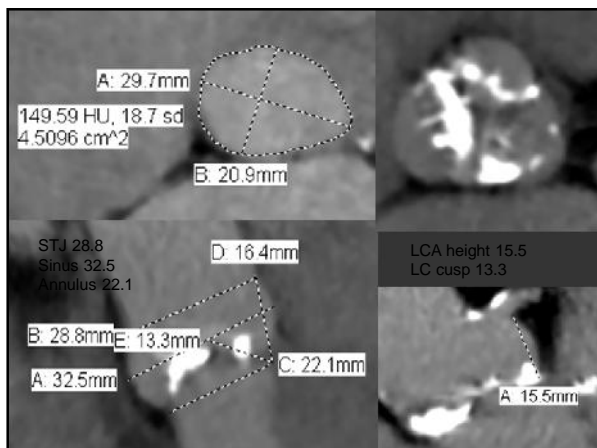


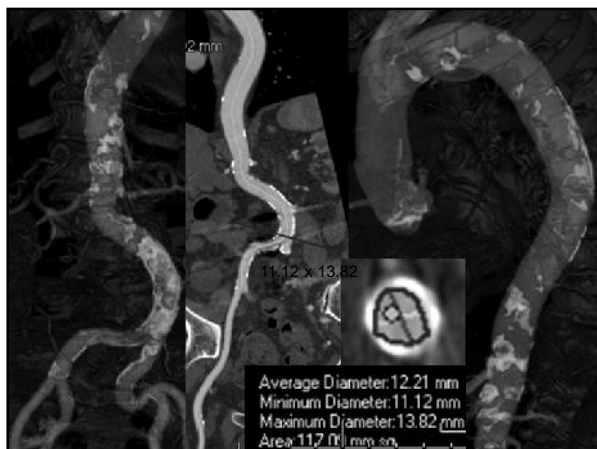
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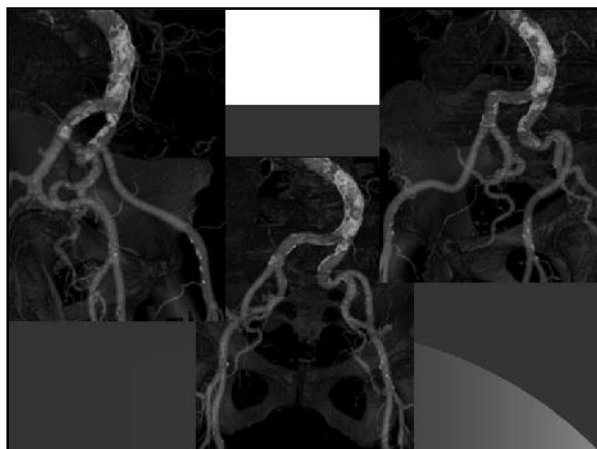
Potential Recommendations:

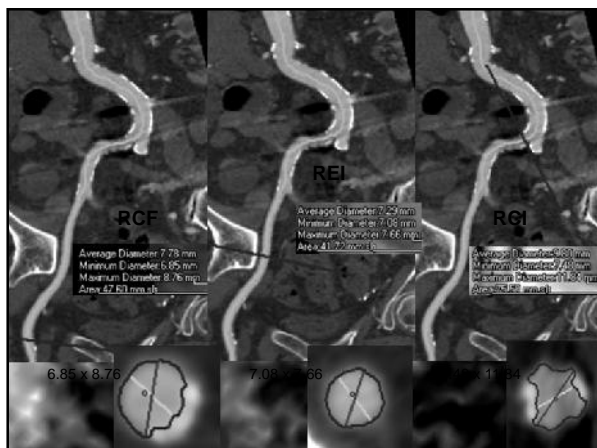
-  Routine Valve Surgical Valve Replacement
 - Aortic
 - Mitral, tricuspid
-  Percutaneous Valve Replacement
 - Edwards Sapien (Aortic)
 - Evalve Mitraclip (Mitral)
-  Continued Medical Therapy
 - Consider balloon valvuloplasty
 - Consider Connections consult
 - Continued Observation

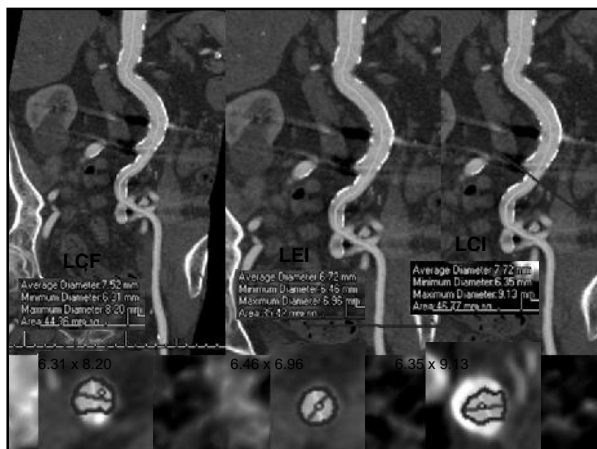








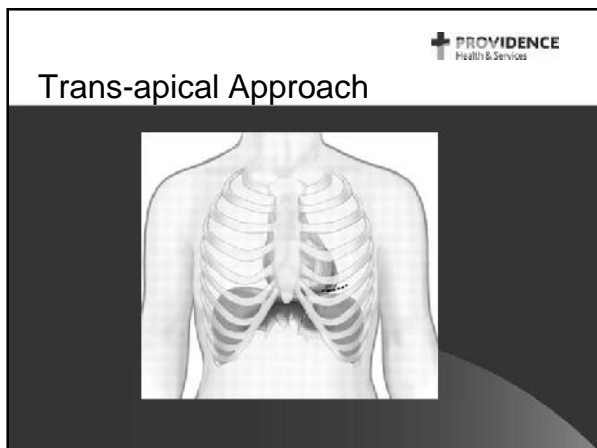


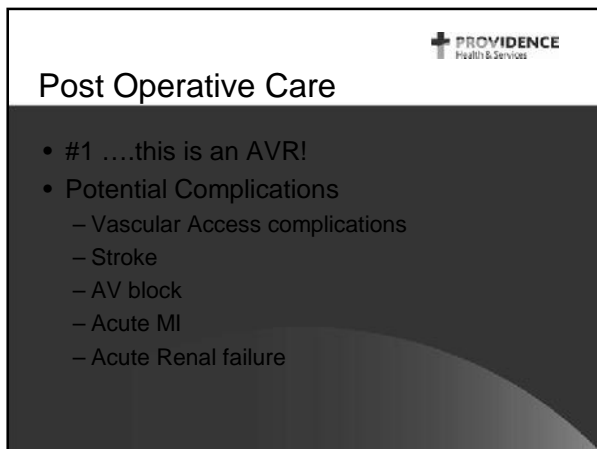


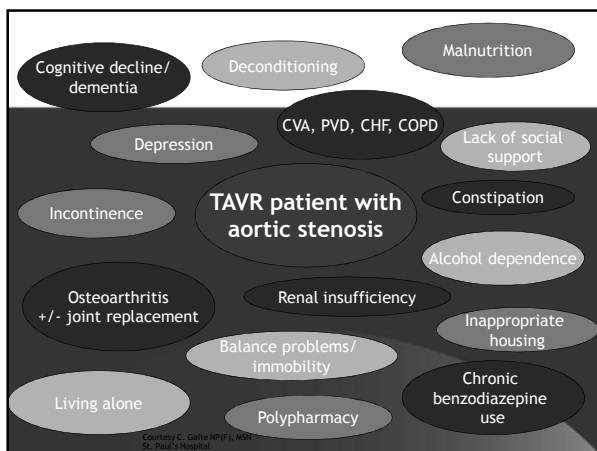
Attention to detail


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 or Providence-UPMC)

Providence St. Vincent Medical Center
3333 Ave. Jerome Drive
Portland, OR 97201
P: 503-254-2000
F: 503-254-0700
800-333-3333

Northwest Portland Medical Center
Atrium Care Center
Portland, OR 97201
P: 503-254-2000
F: 503-254-0700
800-333-3333

Date of Referral: _____ Patient Name: _____ DOB: _____ E-mail: _____
 M: _____ F: _____ MRN (if available): _____ Referring Physician: _____
 Patient Reason: _____ (Please include if forward/echo/egder. Also, for _____
 Patient Address: _____ (Include zip/phone if it begins the fax)
 Alternate contact Name: _____ Home _____

Consultor Requested:
 "Consultor Requested" by "No" If yes, number to call _____
 Referring Physician will see patient in Valve Center (in case of availability/leave travel) Visit No: _____
 If yes, visit number to contact: schedule _____

Appropriate In-Letter Referral Request:

- All referrals are processed through the Providence Valve Center
- Standard referral request requires the cardiac catheterization, CT chest and/or femoral artery, additional views and imaging, medical history of aortic disease.
- Cases are referred to Providence Valve Center on a case-by-case basis for a number of reasons. This includes:
 - o coordination of multidisciplinary care for aortic disease
 - o better outcomes
 - o patient-based approach to surgery
 - o emerging minimally-invasive or hybrid approaches

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 _____ Valve Care _____ (the first request 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/fluoroscopic studies | <input type="checkbox"/> Cardiac Catheterization |
| <input type="checkbox"/> Hematology/pathology consultation | <input type="checkbox"/> Stress Test |
| <input type="checkbox"/> Cardiac/catheterization | <input type="checkbox"/> Other _____ |

Please indicate which records are New and which are old!

THANK YOU

valvecenter@providence.org
