Structural Heart Disease:  
*Setting the Stage for Success*

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To date  
460+ TAVRS  
45+ MitraClip  
12+ Watchman

In 2016  
- 3,600+ coronary & peripheral procedures  
- 1,000+ electrophysiology procedures  
- 800 open heart surgeries  
- 32 VAD implants

Learning Objectives

1. Define the scope of structural heart disease.
2. Adapt principles of program development when developing your structural heart services.
3. Differentiate between various procedures done for structural heart disease.
What is Structural Heart Disease (SHD)?

- Describes non-coronary artery disease procedures & treatments
- Emerging within cardiovascular medicine as its own sub-specialty
- More medical training programs are adding an additional year to interventional cardiology fellowship for SHD experience
- Will continue to evolve with emerging technology & our aging population
- Program development & on-going support is essential for sustained success & growth

Scope of Structural Heart Disease

- Valvular heart disease treatment
- Paravalvular leak repair
- Left atrial appendage closure
- Hypertrophic cardiomyopathy treatment

Steinberg et al, 2010

Keys to a Successful Program

- Planning
- Executing
- Monitoring
- Evaluating
- Revising

Planning

- Name a single point of contact
- Identify key stakeholders
- Develop steering committee
- Outline communication plan
- Determine anticipated patient flow
- Define education plan
- Complete a gap analysis
In 2012, our HEART TEAM started with 2 interventional cardiologists, 2 CV surgeons, 1 imaging cardiologist, 2 anesthesiologists, a CNS, & representatives from Perfusion, Cath Lab, CVOR, & ICU/tele.

### Our Heart Team in Action

**Executing**

- Communicate often with the team
- Practice ‘dry runs’ & worst case scenarios
- Debrief each case, share learnings with the entire team
- Implement rapid cycle tests of change
- Develop specific quality indicators to monitor
- Market to your referral base

**Monitoring**

- Follow patient outcomes closely
- Communicate with referral base
- Participate in registries, research
- Assess impact on other services, procedures
- Evaluate impact on ICU beds, tele beds, hospital throughput
- Review costs, billing, revenue, FTE utilization
Evaluating & Revising

- Evaluate patient outcomes critically
- Reassess processes & streamline when possible
- Continue debriefs, rapid cycle tests of change
- Re-evaluate program when adding new staff/new procedures
- Consider consider LEAN/Six Sigma techniques

REVIEW OF PROCEDURES

Treating Aortic Stenosis (AS)

- Most common acquired valvular disorder, increasing with aging population
- Leads to chest pain, syncope, heart failure, death
- 1st USA device for interventional treatment of AS - FDA approved 2011
- Indicated for high-risk surgical candidates; increasingly being done for moderate-intermediate risk patients
- Femoral approach most common
- General anesthesia still commonly used, typical LOS 3-4 days

Who's a Candidate for TAVR?

Transcatheter Aortic Valve Replacement

- Severe AS: aortic valve area less than 0.8 cm² with peak gradient $\geq$ 40 mmHg
- Reasonable life expectancy
- Increased surgical risk due to co-morbidities
- Anatomy amenable to valve placement
- Poor outcomes more common in patients with wheelchair dependency, prior open heart surgery, oxygen dependency, low serum albumin, high STS risk score

Harjai et al
Percutaneous aortic valves: (A) Edwards-Sapien (Edwards Lifesciences, CA, USA). (B) Fluoroscopic image of Edwards-Sapien device in place. (C) CoreValve (Medtronic-Corevalve, MN, USA). (D) Aortogram with CoreValve in place.

**TAVR Procedural Complications**

- Paravalvular Leak (acute aortic insufficiency)
- Heart block & arrhythmias
- Vascular bleeding/injury
- Stroke
- Acute kidney injury
- Uncommon complications: device embolization/thrombus, annular rupture, aortic dissection, ventricular perforation/rupture, acute MI, conversion to open heart surgery, death

Harjai et al
Treating Mitral Regurgitation (MR)

- Common valvular lesion
- Leads to heart failure, pulmonary hypertension, AF, stroke, death
- MitraClip – approved for treatment of functional MR
- Requires transseptal approach, typically done with general anesthesia, TEE imaging
Transseptal Approach

- Increasingly done with complex arrhythmia ablation & structural heart disease procedures.
- Needed for access to the left heart
- Required for mitral valve procedures, left atrial appendage closure
- Risks include puncture of aorta, perforation of atrium, stroke

Who’s a Candidate for MitraClip?

- Sever MR - 3-4+
- Failing maximal medical therapy for heart failure
- Reasonable life expectancy
- Prohibitive surgical risk due to co-morbidities
- Anatomically amenable to clip placement

MitraClip Procedural Complications

- Access site bleeding, need for blood transfusions
- Device embolization or partial clip deployment
- Longer term complications may include mitral stenosis, infective endocarditis

Paravalvular Leak (PVL) Repair

- Uncommon complication of valve replacement surgery
- Signs & symptoms of significant leak may include heart failure, hemolysis
- Reserved for symptomatic high-risk patients with suitable anatomy
- Percutaneous approach often preferred to prevent re-operation as surgical re-intervention is associated with high morbidity & mortality
PVL Repair

- Multiple devices available for use – occluders, plugs
- Technically challenging procedure; careful imaging is important – cardiac CT, 3D TEE, intracardiac echocardiography (ICE)

Lasala et al

Left Atrial Appendage (LAA) Closure

- Atrial fibrillation (AF) increases risk of embolic stroke
- Most emboli (90%) originate from the LAA.
- Device closure may be beneficial for patients with chronic AF who are unable to take anticoagulation.

Beigel et al

Left atrial appendage closure (LAA) occluders: (A) Watchman (Atritech, MN, USA). (B) Amplatzer APC (AGA Medical, MN, USA).

Hypertrophic Cardiomyopathy

- Marked hypertrophy of the septum
- Genetic autosomal-dominant disease
- Occurs in 1 in 500 people; 600,000 people affected in the US
- Increase risk of arrhythmias, sudden cardiac death, angina, syncope & heart failure
- Treatment options include medical therapy, dual chamber cardiac pacing, surgical ventricular myotomy-myomectomy, alcohol septal ablation

Gersh et al

Treating Hypertrophic Cardiomyopathy

- Alcohol Septal Ablation

- 96% ethanol introduced into a septal branch of the left anterior descending artery
- Ablates the artery, induces infarction with stunning & remodeling

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>Does not require open heart surgery &amp;/or cardio-pulmonary bypass</td>
<td>Produces large infarct with potential for arrhythmia/heart block</td>
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<tr>
<td>Shorter LOS</td>
<td>May require repeated intervention</td>
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<td>In-hospital mortality 4%</td>
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<td>Need for permanent pacemaker 5-33%</td>
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Gersh et al
IDEAS FROM SMCS

Infrastructure Needs

- Clinic space for patient evaluation
- Access to high quality imaging: 3D echo, cardiac CT/CTA
- Hybrid cath lab/CVOR – large physical space, surgical air exchanges, high quality imaging equipment with integrated imaging (CT/echo) systems, multiple large display monitors
- Large inventory of disposables: many new sheaths, catheters, wires, devices
- PACU & ICU accustomed to caring for CV surgical patients

Determine Patient Flow

Typical flow for closures, Watchman procedures

Typical flow for TAVRs, MitraClip, & PVL repair procedures
### Marketing to Your Referral Base

**In Closing**

- Program strength & growth aided by thoughtful planning, careful execution, close monitoring of outcomes & costs, effective evaluating, & on-going revisions
- Interventional management of structural heart disease will continue to develop as technology improves & transforms
- Emerging areas for future growth include mitral & tricuspid valves replacement/repair, valve-in-valve, stroke prevention procedures

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### Staff Education

**What are the PACU key priorities of care following the WATCHMAN procedure?**

- Connecting to monitoring systems, receiving report from the Anesthesiologist and the circulating RN.
- Maintaining airway and re-orientation.
- Continuous cardiac monitoring, hemodynamic assessment.
- Assessing access sites and vital signs every 15 minutes.
- Assessing neuro status on arrival.

**What did we do?**

1. Moved from surgical cutdown to percutaneous approach; vascular closure devices used.
2. Moved away from transapical approach.
3. No Swan, no Foley, lighter anesthesia, more procedural sedation.
4. All lines pulled 2-4 hours after ICU arrival if patient hemodynamically stable without pressors/pacing.
5. 1st & 2nd patients of the day transferred to telemetry 6-8 hours after ICU arrival when criteria met.

**Who are my resources when I have questions?**

- Cath lab staff involved in the case.
- Dr. Robert, Dr. Huang, Anesthesia Provider.

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### PDSA example

**average TAVR ICU LOS in hours**

**Goal: Decrease ICU length of stay**

About 50% decrease over 3 years.

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**SMCS 2016 Total LOS = 2.6 days**
References

Beigel R et al. The left atrial appendage: Anatomy, function, and noninvasive evaluation. JACC: Cardiovascular Imaging 7(12), 1251-65.


