The Future of Structural Heart Therapeutics

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Areas of Development

- Aortic Valve Therapeutics
- Mitral Valve Therapeutics
- Paravalvular Leak Repair
- Heart Failure - Parachute Trial

Disclosures
Consultant for St. Jude, Edwards Lifescience and Medtronic
PI at KU for the COAPT Trial (Abbott vascular)
PI at KU for the PARACHUTE Trial
Aortic Valve Therapeutics - TAVR 2016
Global Demographics and Economics

_Tremendous Growth_

Over the next decade 4X growth in TAVR procedures predicted, associated with...
- faster growth in the US, Japan, and ROW
- marked regional growth heterogeneity due to differing reimbursement patterns
- stabilization of trained operator sites
- continued under-diagnosis and under-treatment of AS

Estimated Global TAVR Procedure Growth

In the next 10 years, TAVR growth will increase X4!

2015 Medicare AV Cases

_TAVR now accounts for 31% of all AV replacements_

Aortic Valve Therapeutics
Current State and Future directions

- Has the original goal of TAVR, to provide a meaningful and less-invasive option for AS patients been achieved?
  - Mortality
  - Stroke
  - Durability
  - PVL
Aortic Valve Therapeutics
Current State and Future directions

- Has the original goal of TAVR, to provide a meaningful and less-invasive option for AS patients been achieved?

**Mortality**

- Stroke
- Durability
- PVL

**PARTNER Study Design**

Mortality - Extreme High Risk

**All-Cause Mortality (ITT)**

Crossover Patients Censored at Crossover

- Standard Therapy (n = 311)
- St. Jude (n = 138)

*Average and gender matched US population without comorbidities, the mortality at 1 year was 14.3%.
**Only 2 standard St. Jude patients were alive at 3 years who didn’t crossover to having their aortic valve replaced.*

**Mortality**

**All-Cause Mortality (ITT)**

- Standard Therapy: 11.1 Months
- TAVR: 29.7 Months

*p (log-rank) < 0.0001*
Mortality - High Risk

PARTNER Study Design

Total Trials Design

All-Cause Mortality (ITT) All Patients

The PARTNER 2A and S3i Trials Study Design

Intermediate Risk Symptomatic Severe Aortic Stenosis

Primary Endpoint: All-Cause Mortality, All Stroke, or Major/Mild AR at One Year (Non-inferiority Propensity Score Analysis)
Unadjusted Time-to-Event Analysis
All-Cause Mortality (AT)

Number of risk:
PDA Surgery Arm
S3 TAVR 1977
859
1043
1017
991
963

All-Cause Mortality (%)
0
10
20
30
40
50
7.4%
13.0%
1.1%
4.0%

Number at risk:
S3 TAVR
P2A Surgery

Months from Procedure
0
3
6
9
12

SAPIEN Platforms in PARTNER
Device Evolution

Valve Technology
SAPIEN
SAPIEN XT
SAPIEN 3

Dilute Compatibility
22-24F
18-20F
14-16F

Available Valve Sizes
21 mm
25 mm
29 mm
23 mm
26 mm
29 mm
31 mm

CoreValve High-Risk U.S. Pivotal Trial

CoreValve US Pivotal Trials Design

Extreme Risk
High Risk
Randomization 1:1

CoreValve US Pivotal Trials
CoreValve Non-Biofemoral
CoreValve Biofemoral
SAVR

CoreValve

Aortic Valve Therapeutics
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  - Durability
  - PVL
Durability with TAVR - 2016

The Durability Controversy

Until there is long-term (>10 years) reliable clinical and echo data on normal-risk patients treated with “modern era” transcatheter bioprosthetic valves, there will always be concerns regarding “durability”!

Aortic Valve Therapeutics
Current State and Future directions

- Has the original goal of TAVR, to provide a meaningful and less-invasive option for AS patients been achieved?
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5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial

5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1): a randomised controlled trial
Aortic Valve Therapeutics
Current State and Future directions

- Has the original goal of TAVR, to provide a meaningful and less-invasive option for AS patients been achieved?
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  - Stroke
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  - PVL

TAVR in 2016
Controversies

Paravalvular Regurgitation

- Is paravalvular regurgitation (PVR) after TAVR associated with increased mortality?
- What are the causes of PVL?
- Can many of the predictors be identified by screening MSCT, 3D echo result inoptimal valve sizing and reduce PVL?
TAVR 2016 - current state

- Lower mortality and stroke than SAVR has been shown in high risk and intermediate risk patients
- Pacemaker rates are around 10%
- Strokes rates have declined and are lower than SAVR
- Significant PVL rates are low
Next Generation TAVR Systems
Not All New TAVR Systems are Self-Expanding Designs

Direct Flow: Polyester fabric cuff with two inflatable rings; positioning wires for placement; bovine tissue valve

Saphenous: Nitinol wire frame, bovine tissue valve; mechanical expansion and locking

Sapien 3: balloon exp (4 sizes), cobalt frame; bovine tissue valve; outer skirt; precise positioning

Questions?

"Not all those who wander are lost"

Mark Wiley, MD
University of Kansas Medical Center

Percutaneous Mitral Valve Therapeutic
Today, we are going to be talking about mitral regurgitation (MR). First, we'll start with the classification and etiology of MR, which is directly related to how you evaluate and manage these patients. Next, we will discuss the prevalence. MR is highly prevalent among the elderly, and this is an underserved patient population. Third, we will go over the natural history and key prognostic determinants. Then, finally, we will talk about what you need to know in terms of choosing appropriate therapy for your patients.

Etiology of Mitral Insufficiency

- **Degenerative MR** (Primary)
  - Also known as primary or organic MR
  - Usually caused by an anatomic defect of one or more structures comprising the mitral valve apparatus—the annulus, the leaflets, the chordae tendineae, and the papillary muscles.

- **Functional MR** (Secondary)
  - Also known as secondary MR
  - Results from left ventricular (LV) dysfunction and dilation, which causes otherwise normal valve components to fail and results in MR.

**Classification of Mitral Insufficiency**

- **Primary**
  - "The Valve"
  - Usually myxomatous

- **Secondary**
  - "The Ventricle"
  - Ischemic or not

**Degenerative Mitral Insufficiency (Primary)**
Degenerative Mitral Insufficiency

Key Prognostic Determinants

- Severity
- Left Ventricular Function
- Symptoms

Asymptomatic Degenerative Mitral Insufficiency

Natural History

Risk Factors:
- Age ≥ 50 yrs
- Atrial fibrillation
- LA enlargement
- Flail leaflet
- Mild MR

MR ≥ 3+ or EF < 50%

The natural history of mitral insufficiency is affected by several risk factors. The most significant of which is MR >3+ or an EF <50%. In this population-based study, either one of these was a 10 yr survival of only 55%.

Other risk factors included age over 50, AF, LAD, flail leaflet or mild MR. Two or more of these was worse than one.

Symptomatic Degenerative (Flail) Mitral Insufficiency

Natural History

Classification of Mitral Regurgitation

Primary
- “The Valve”
- Usually myxomatous

Secondary
- “The Ventricle”
- Ischemic or not

The impact of symptoms is magnified in the presence of flail mitral leaflet. The risk of death is about 4% yearly for patients with mild or no symptoms. The risk of death with severe symptoms or decompensated heart failure was very high with a noted annual mortality of 34%.
Functional (Secondary) Mitral Insufficiency
A Ventricular Problem

- Papillary muscle displacement
- Annular flattening
- Leaflet tethering

Regional or Global Dysfunction


Mitral Insufficiency and Heart Failure Prevalence in Heart Failure

- Moderate or severe MR present in ~40%
- ~4 million people with heart failure and MR in U.S.


Advanced Heart Failure

- None
- Moderate
- Mod-Severe
- Severe

Mitral Regurgitation Progresses to Heart Failure

- MR initiates a cascade of events progressing to heart failure, then death, if untreated
- Mortality up to 57%

- Dilation of Left Ventricle
- Dysfunction of Left Ventricle
- Muscle Damage/ Loss
- Increased Load/ Stress

The presence of MR sets in a vicious cycle of worsening LV size/stress. 
MR leads to an increase in the preload of the LV, which leads to worse dilation, followed by worsening of the MR. Thus, MR leads to increase mortality and HF.

Mitral Valve Disease is Common and Increases with Age

- Mitral Regurgitation (MR) is the most common type of heart insufficiency in the US.

Prevalence of Valvular Heart Disease by Age

- The prevalence of MR is about 6% for those over 65, and 9% for those over 75.

- This prevalence is expected to increase as the population ages.

- Given the rapid aging of our population, MR is only going to be more common in our clinical practice.

Mitral Regurgitation

- Given the scope of Mitral Valve disease and that untreated severe Mitral Insufficiency increases morbidity and mortality...

- What are the options for therapy?
General Principles of Therapy

<table>
<thead>
<tr>
<th>Primary</th>
<th>Secondary</th>
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<tbody>
<tr>
<td>No medical option</td>
<td>Medical therapy first</td>
</tr>
<tr>
<td>Surgery for symptoms or LV dysfunction</td>
<td>Consider CRT</td>
</tr>
<tr>
<td>Try to repair</td>
<td>Surgery only in highly selected patients with HF</td>
</tr>
<tr>
<td>Consider prophylactic repair</td>
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</table>

Primary Mitral Insufficiency

**Timing of Surgical Intervention**

**ACC/AHA Guidelines – Primary MR**

**Consider surgery when**

- Symptoms
- or
- LV dysfunction (EF<60%, ESD≥40 mm)

**Try to repair in a experienced center**

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2014 AHA/ACC Guidelines for the Management of Patients with Valvular Heart Disease

**MitraClip Repair**

*Class IIb

3. Transcatheter mitral valve repair may be considered for severely symptomatic patients (NYHA class III to IV) with chronic severe primary MR (stage D) who have favorable anatomy for the repair procedure and a reasonable life expectancy but who have a prohibitive surgical risk because of severe comorbidities and remain severely symptomatic despite optimal GDMT for HF (428). (Level of Evidence: B)*

An RCT of percutaneous mitral valve repair using the MitraClip device versus surgical mitral repair was conducted in the United States. The clip was found to be safe but less effective than surgical repair because residual MR was more prevalent in the percutaneous group. However, the clip did reduce severity of MR, improved symptoms, and led to reverse LV remodeling. Percutaneous mitral valve repair should only be considered for patients with chronic primary MR who remain severely symptomatic with NYHA class III to IV HF symptoms despite optimal GDMT for HF and who are considered inoperable.*

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Concept: Transcatheter Mitral Valve Repair

- Double-orifice suture technique developed by Prof. Ottavio Alfieri
- First published results in 1998 illustrated proven benefit
- Suggested procedure best suited for minimally invasive approach

- Dr. Fred St. Goar, interventional cardiologist had patient successfully treated with edge-to-edge surgery
- Conceived several ideas for percutaneous valve repair
- Founded Evalve 1999 to develop devices to treat valvular disease

The MitraClip System Benefits

- Ability to accurately position and reposition
  - Mitral repair without arresting the heart (no need for cardiopulmonary bypass)
  - Mitral regurgitation assessed in real time within beating heart, allowing repositioning of the clip until desired outcome is obtained
  - Surgical intervention remains preserved

MitraClip Therapy
Filling a Treatment Gap

- Medical therapy is limited to symptom management
- MV surgery has been the only option that reliably reduces MR
- A significant gap exists between medical and surgical options
- MitraClip therapy is a first-in-class, percutaneous option to reduce MR

MitraClip® System

Venous access under general anesthesia
Clip is optimally positioned on MR jet
Creation of double-orifice valve
Clip repositioned until desired outcome is obtained

MitraClip Therapy
Filling a Treatment Gap

- Medical therapy is limited to symptom management
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Medical Therapy

MitraClip®

MV Surgery

Increased MR Reduction
Primary Mitral Insufficiency
Patients Indicated for Surgery on OMT

What Therapy for Primary MR?
Based on Patient Risk

- Not High
- High
- Surgery
- MitraClip

Degenerative Mitral Insufficiency
Baseline pre-clip

Initial Mitraclip Deployment

Mitraclip Second Clip Deployment
Post Mitraclip

**Prohibitive Surgical Risk**

DMR Cohort (n=127)

- Age: 82 ±9 years
- Prior MI: 24%
- Prior stroke: 10%
- Diabetes: 30%
- COPD: 32%
- Renal disease: 28%

Mean STS Risk 13.2%


**MitraClip® Experience**

- **EVEREST I Feasibility** (n=55)
- **EVEREST II Pivotal**
  - Pre-Randomization (n=60)
  - HR Registry (n=78)
  - Randomized (2:1 Clip to Surgery) (n=279)
- **REALISM Registry**
  - Continued Access (n=965)
- **Worldwide Commercial Use:** >15,000 patients

In the United States, experience with the mitraclip technology started with the EVEREST feasibility and pivotal studies, followed by a continued access registry of nearly 1,000 patients. The device received CE mark in Europe in 2009. Thus far, there have been more than 15,000 patients worldwide who have been treated with mitraclip therapy.

In this population the implant success rate was very high at 95% with no procedural deaths. The average one year survival was 90% or greater, remarkable for this sick population of patients.

95% implant success
No procedural deaths
LOS = 2.9 days

Clinically Important Results in Prohibitive Risk DMR Patients

**Mitra Regurgitation Grade**

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<thead>
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<tr>
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<tr>
<td>9</td>
<td>90%</td>
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<tr>
<td>10</td>
<td>100%</td>
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**NYHA Functional Class**

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<td>80%</td>
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<tr>
<td>IX</td>
<td>90%</td>
</tr>
<tr>
<td>X</td>
<td>100%</td>
</tr>
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**Hospitalizations for Heart Failure**

- Baseline: 10
- 1 Year Prior to MitraClip: 7
- 1 Year Post Discharge: 2

75% Reduction

**Left Ventricular Volumes**

- Baseline: 16 mL
- 1 Year Prior to MitraClip: 49 mL
- 1 Year Post Discharge: 46 mL

Source: MitraClip Clip Delivery System Instructions for Use

General Principles of Therapy

**Primary**

- No medical option

**Secondary**

- Medical therapy first
- Surgery for symptoms or LV dysfunction
- Try to repair
- Consider prophylactic repair

Surgical Intervention of Secondary Mitral Insufficiency

**ACC/AHA Guidelines – Secondary MR**

*Surgery may be considered for severe symptoms despite optimal GDMT for HF (IIb)*

Surgery for Mitral Insufficiency can also be considered concurrently during other cardiac surgery if Severe (IIa) or Moderate (IIb)

Surgery for Secondary MR

- No mortality benefit

*The indications for surgery for secondary MR are less strong because there is less evidence of any survival or symptom benefit*

In this study by Wu et al., in which highly experienced surgical operators performed surgery for secondary MR, the survival after surgery was exactly the same as with medical therapy.

Surgical Repair doesn’t necessarily fix the underlying cause!
**Trial Design**
Goals: 430 patients at up to 75 US sites
Significant FMR (3+ by core lab)
Symptomatic heart failure subjects who are treated per standard of care
Determined by the site's local heart team as not appropriate for mitral valve surgery
Specific valve anatomic criteria
Randomize 1:1

- MitraClip N=215
- Control group Standard of care N=215

Clinical and TTE follow-up:
Baseline, Treatment, 1-week (phone)
1, 6, 12, 18, 24, 36, 48, 60 months

**Purpose**
- COAPT is a landmark trial to further study the MitraClip device in symptomatic FMR patients with heart failure
- The study will generate important clinical and economic data to support reimbursement and evidence to support the development of treatment guidelines
- COAPT is the first randomized controlled clinical trial to compare non-surgical (medical) standard of care treatment to a percutaneous intervention to reduce MR

**(Secondary) Functional MR**
- 78 y/o AAF who presented with multiple admissions for acute decompensated systolic heart failure
- Echocardiogram demonstrates and EF of 20% - NICM
- COPD
- HTN
- PAF on chronic Anticoagulation
- h/o DVT
- h/o CVA

**COAPT Trial**
- Was optimized medically and with CRT-D
- Managed by Advanced Heart Failure physician and team to ensure OMT
- Randomized to mitraclip
Mitraclip Deployment

- Initial clip was positioned and deployed
- Goal was to reduce MR grade by 2+
**Key Points**

- **Prevalence** is age-dependent, affecting 9.3% of those aged >75 years.
- **Etiology** is primary (i.e., valvular) or secondary (i.e., ventricular).
- Excess mortality occurs from medical management and delays in intervention.
- Surgical risk and etiology determine intervention and its timing.

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**Mitral valve - what's next?**

**TMVR**

**Tendyne Transcatheter Mitral Valve**

**Procedural Steps**

1. Insert Catheter into LA
2. Intra-Anular Deployment
3. Ensure Valve Seating
4. Adjust Tether Tension
5. Secure Apical Pad

**Tendyne Procedure**

- Fully Reconfigurable
- Fully Retrievable
- No Rapid Pacing or CPB
The Next Frontier...

PRINCIPLES OF PARAVALVULAR LEAK REPAIR

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University of Kansas Medical School

CONFlict OF INTEREST

- Consulting agreements
  - St. Jude Medical
  - Edwards Lifescience
  - Medtronic

2015 Iceland
**BACKGROUND**

**SCOPE OF THE ISSUE**

- Approximately 80-85,000 AVR’s are performed annually
- Approximately 2% of >3+ MR patients are treated with MVR (35-45,000)
- ~115,000 - 130,000 patients treated with valve replacement and this number is trending up with TAVR
- Currently valve therapies and treatment options are continuing to expand with significant growth in transcatheter based valve replacement.

**BACKGROUND**

**SCOPE**

- Transcatheter based valve replacement tends to have had higher rates of paravalvular leak.
- up to 17% demonstrate moderate to severe PVL
- Next generation devices are designed to minimize PVL and are doing a better job…

**PARAVALVULAR LEAK REPAIR**

- Currently, surgical repair has been the standard
- Associated with significant morbidity and mortality

**SURGICAL TREATMENT OF PARAVALVULAR LEAK: LONG-TERM RESULTS IN A SINGLE CENTER EXPERIENCE**

 Objective

- Long term outcomes (median 7 years) of patients who underwent surgery for a PVL.

 Results

- The mean age of patients was 62 ± 11 years.
- Symptomatic hemolysis was present in 31% of the patients, and 41% of the patients had more than 1 previous cardiac operation.
- Paravalvular leak repair was feasible in 79 patients (65%), whereas in 43 patients (35%) prosthesis replacement was required.
- Thirty-day mortality was 10.7% (13/122 patients), 5% for aortic paravalvular leak and 13% for mitral paravalvular leak; P = 1.2 patients (1.6%) with residual severe mitral paravalvular leak underwent successful redo surgery before discharge.
- Overall actuarial survival was 39% ± 6% at 12 years; freedom from cardiac death was 54% ± 7% at 12 years.

 Conclusion

- The operative mortality of surgical treatment of paravalvular leak is still high. Long-term outcomes remain suboptimal in these challenging patients, especially in the presence of multiple previous cardiac operations and associated co-pathologies. These results support the importance of alternative therapeutic options.
AORTIC PARAVALVULAR REGURGITATION

• Aortic leaks are less frequent and tend to be less symptomatic than paravalvular mitral leaks
  • 1-5% of surgical aortic valves
  • 60% are evident in the first year
  • Aortic leaks are most often closed via a direct retrograde aortic approach

MITRAL PARAVALVULAR REGURGITATION

• 2-12% incidence after mitral valve surgery
• Patients tend to be more symptomatic with associated hemolysis
• Occur more frequently because of a severely diseased annulus or friable tissue

PATIENT EVALUATION

• Patient history
  • Is there prior endocarditis?
  • Has the patient been fully treated?
  • Is hemolysis present at baseline?
• Lab evaluation
  • ESR/CRP
  • CBC with Diff/peripheral smear
  • LDH/Haptoglobin/plasma free hemoglobin

PVL CLOSURE

MITRAL OR AORTIC

• Imaging
  • Preprocedure CT
  • TTE or ICE guidance
  • ICE can be advanced into the RVOT to better evaluate the aortic valve
  • Standard imaging is 3D TEE
PVL CLOSURE

• Utilize Aortography to assist in assessing severity when imaging and clinical picture don't match.

• Color Doppler can over estimate the severity of leak. “garden hose effect”

• Acoustic shadowing may give a false impression of mild paravalvular regurgitation when severe is present

LOCALIZE THE LEAK

• Get in sync with your team

• agree upon nomenclature for the description of the valve (we typically use clock face orientation)

• Mitral valve - use the “surgical view” rotate the aortic valve to the top (anterior) in en face view

• Aortic valve - similarly use an en face view

CASE REVIEW

PROCEDURAL PLANNING

• PLANNING YOUR APPROACH
  • ANTEROGRADE
    • TYPICAL MITRAL APPROACH
  • RETROGRADE
    • AORTIC APPROACH
    • TRANSCAPITAL
    • MEDIAL MITRAL DEFECT?

CHOSE YOUR DEVICE WISELY

Device should match the anatomy!
Case 1
Endocarditis
“Triple Jeopardy”
- 62yo male with a bicuspid valve, underwent AVR 10/2012
- Developed endocarditis and have repeat AVR 1/2013
- Developed worsening shortness of breath and paravalvular insufficiency
- Functional status declined to a wheelchair bound state

Case 1
Endocarditis
“Triple Jeopardy”
- Imaging demonstrated a large paravalvular leak
- Patient was referred for surgical opinion
- Infectious disease completed endocarditis coarse and antibiotics were discontinued
CASE 1
ENDOCARDITIS
“TRIPLE JEOPARDY”

- No surgical options
- Deployed an 8mm VSD occluder device and staged a second procedure
- Second stage procedure - Deployed a 12mm AVP2

- Post procedure echo demonstrated a residual mild to moderate leak
- Symptomatically the patient is now exercising on a treadmill

DEVICE SPECS

- VSD occluder
  - 8mm waist
- AVP II
  - 12mm diameter

EQUIPMENT PROGRESSION

- 8F 90cm Terumo destination
- Advanced an AL1 6F catheter to direct an 0.014 luge wire.
- Exchanged using an 0.035 Quick cross and advanced an 0.035 Amplatz superstiff wire
- The terumo was then advanced into the left ventricle and the 8mm VSD device was deployed
EQUIPMENT/PROGRESSION

- 8F shuttle sheath
- AL2 catheter to direct an 0.014 PTMS - advanced an 0.018 quick cross and exchanged the wire for an 0.018 steel core wire.
- 5F glide cath advanced and exchanged for an 0.035 Amplatz Super Stiff wire.
- We then needed to readvance the AL2 to “telescope” the shuttle sheath in to the LV.
- AVP2 deployed.

CASE 2
COREVALVE IN COREVALVE

- 85 y/o male with severe aortic stenosis -s/p TAVR with #29 Medtronic Corevalve 9/1/2011. Implant depth was 5mm
  * residual 2+ PVL
- 2/13/2011 - persistent residual paravalvular leak. 2nd TAVR with #31 Medtronic Corevalve

CASE 2
COREVALVE IN COREVALVE

- Given progressive dyspnea with exertion and persistent PVL he underwent PVL closure
- Initial placement of 22mm AVP II plug
- Mild reduction in the PVL, however still moderate to severe
- Planned a staged procedure

CASE 2
COREVALVE IN COREVALVE

- Moderate to severe persistent PVL with multiple jets.
- Patient continued to be symptomatic, however had improved clinically.
**CASE 2**
**COREVALVE IN COREVALVE**

- Staged procedure was planned to treat persistent PVL.
- Successful deployment of an 6-6-12mm ADO II device with significant improvement in residual PVL.

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**DEVICE SPECS**

- AVP II
  - 22mm

- ADO II
  - 6-6-12mm

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**EQUIPMENT PROGRESSION**

- 8F Shuttle sheath
- V-tech catheter and advanced an 0.014 PTMS and exchange for a steelcore.
- Advanced a 9X20mm EverCross into the space and inflated. This confirmed a reduction in PVL and was used as an anchor to advance the Shuttle sheath.
- Advanced the Shuttle sheath into the LV and deployed the AVP II while maintaining the 0.018 Steelcore.
CONCLUSION

- Aortic PVL closure is a safe viable option and should be considered in symptomatic patients.

Apical Exclusion - Percutaneous Dor Procedure

In 1985, Vincent Dor, MD, introduced endoventricular circular patch plasty (EVCPP), or the Dor procedure, as a viable method for restoring a dilated left ventricle to its normal, elliptical geometry.

Surgical Dor Procedure

Parachute - Apical excluder