New Approaches to Valve Repair and Replacement

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Disclosures
No financial conflict
Member of Steering Committee for COAPT
Member of TVT mitral working group
Scope

- Mitral Valve
  - MitraClip
  - Mitral valve replacement
- Aortic Valve
  - Replacement
  - Valve in vale
- Paravalvular leak closure
Percutaneous Mitral Valve Therapies

- Repair
  - Edge to edge - MitraClip
  - Annuloplasty
  - Artificial cords
  - External pads
  - “Spacer”

- Replacement
## Functional MR

<table>
<thead>
<tr>
<th>Device design</th>
<th>Development phase</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Leaflet techniques</strong></td>
<td></td>
</tr>
<tr>
<td>Edge-to-edge leaflet repair</td>
<td></td>
</tr>
<tr>
<td>MitralClip™ (Evalve, Menlo Park, CA)</td>
<td>Phase III trials</td>
</tr>
<tr>
<td>MOBIUS (Edwards, Lifesciences, Irvine, CA)</td>
<td>Development halted</td>
</tr>
<tr>
<td>MitraFlex (TransCardiac Therapeutics, Altanta, GA)</td>
<td>Preclinical phase</td>
</tr>
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<table>
<thead>
<tr>
<th>Leaflet Space Occupiers</th>
<th></th>
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<tbody>
<tr>
<td>Percu-Pro (Cardiosolutions, Stoughton, MA)</td>
<td>Phase I trials</td>
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<table>
<thead>
<tr>
<th>Anuloplasty</th>
<th></th>
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<tbody>
<tr>
<td>Indirect (via coronary sinus)</td>
<td></td>
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<tr>
<td>Viacor PTMA (Viacor, Wilmington, MA)</td>
<td>Development halted</td>
</tr>
<tr>
<td>CARILLON™ Mitral Contour System (Cardiac Dimensions, Kirkland, WA)</td>
<td>First-in-human</td>
</tr>
<tr>
<td>MONARC™ (Edwards Lifesciences, Irvine, CA)</td>
<td>Development halted</td>
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<tr>
<td>St.Jude adjustable annuloplasty ring (St Jude Medical, St Paul, MN)</td>
<td>Animal models</td>
</tr>
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<table>
<thead>
<tr>
<th>NIH-Cerclage technology</th>
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<tr>
<td>Mitralign Percutaneous Annuloplasty System (Mitralign, Tewksbury, MA)</td>
<td>First-in-human</td>
</tr>
<tr>
<td>GDS Accucinch Annuloplasty System (GDS)</td>
<td>First-in-human</td>
</tr>
<tr>
<td>Kardium Cinch (kardium)</td>
<td>Feasibility phase</td>
</tr>
<tr>
<td>Millipede Percutaneous Annuloplasty Ring (MC3, Ann Arbor, MI)</td>
<td>Preclinical phase</td>
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<tr>
<td>QuantumCor device (QuantumCor, Bothell, WA)</td>
<td>Preclinical phase</td>
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<tr>
<td>ReCor (ReCor Medical, Ronkonkoma, NY)</td>
<td>Feasibility phase</td>
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<tr>
<td>Adjustable Annuloplasty Ring (Mitrail Solutions, Fort Lauderdale, FL)</td>
<td>First-in-human</td>
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<td>Dynamic Annuloplasty Ring System (MiCardia, Irvine, CA)</td>
<td>First-in-human</td>
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<td>PS3 System (Ample Medical Inc., Foster City, CA)</td>
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<table>
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<tr>
<th>Left ventricular remodeling</th>
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<td>iCoapsys™ (Myocor, Maple Grove, MN)</td>
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<tr>
<td>BACE device (Phoenix Cardiac devices, Northbrook, IL)</td>
<td>First-in-human</td>
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<tr>
<td>Degenerative MR</td>
<td></td>
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<tr>
<td>----------------</td>
<td></td>
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<tr>
<td><strong>Device design</strong></td>
<td>Developmental phase</td>
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<tr>
<td><strong>Leaflet technique</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Edge-to-edge leaflet repair</strong></td>
<td></td>
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<tr>
<td><em>MitralClip™ (Evalve, Menlo Park, CA)</em></td>
<td>FDA approved</td>
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<tr>
<td><em>MitraFlex (TransCardiac Therapeutics, Atlanta, GA)</em></td>
<td>Preclinical phase</td>
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<td><strong>Leaflet ablation</strong></td>
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<tr>
<td><em>ThermoCool irrigation ablation electrode (BioSense Webster, Diamond Bar, CA)</em></td>
<td>Animal models</td>
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<tr>
<td><strong>Leaflet Space Occupiers</strong></td>
<td></td>
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<tr>
<td><em>Percu-Pro (Cardiosolutions, Stoughton, MA)</em></td>
<td>Phase I trials</td>
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<tr>
<td><strong>Chordal techniques</strong></td>
<td></td>
</tr>
<tr>
<td><em>NeoChord (NeoChord, Minnetonka, MN)</em></td>
<td>Preclinical phase</td>
</tr>
<tr>
<td><em>MitraFlex (TransCardiac Therapeutics, Atlanta, GA)</em></td>
<td>Preclinical phase</td>
</tr>
<tr>
<td><em>V-Chordal Adjustable System (Valtech Cardio Lt, Or-Yehuda, Israel)</em></td>
<td>Early clinical evaluation</td>
</tr>
<tr>
<td><em>Babic neochord</em></td>
<td>Preclinical phase</td>
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# Transcatheter Mitral Replacement

<table>
<thead>
<tr>
<th>Company</th>
<th>product</th>
<th>access</th>
<th>status</th>
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<tbody>
<tr>
<td>Caisson</td>
<td>Caisson TMR</td>
<td>TF</td>
<td>preclinical</td>
</tr>
<tr>
<td>CardiaQ</td>
<td>TMVI-TA</td>
<td>TF / TAp</td>
<td>clinical</td>
</tr>
<tr>
<td>Edwards</td>
<td>Fortis</td>
<td>TAp / TF</td>
<td>clinical</td>
</tr>
<tr>
<td>Emory U</td>
<td>MitraCath</td>
<td>NA</td>
<td>Early develop.</td>
</tr>
<tr>
<td>HighLife</td>
<td>HighLife MVR</td>
<td>TAi</td>
<td>preclinical</td>
</tr>
<tr>
<td>Invalve</td>
<td>Invalve</td>
<td>NA</td>
<td>IP</td>
</tr>
<tr>
<td>Medtronic</td>
<td>TMVR</td>
<td>TAi / TF</td>
<td>preclinical</td>
</tr>
<tr>
<td>Micro Interv. Devices</td>
<td>EndoValve TA</td>
<td>NA</td>
<td>preclinical</td>
</tr>
<tr>
<td>MitrAssist</td>
<td>Mitrassist valve</td>
<td>NA</td>
<td>preclinical</td>
</tr>
<tr>
<td>Mitralix</td>
<td>MAESTRO</td>
<td>NA</td>
<td>Early develop.</td>
</tr>
<tr>
<td>MITRICARES</td>
<td>Mtricares</td>
<td>NA</td>
<td>IP</td>
</tr>
<tr>
<td>NCSI</td>
<td>NAVIGATE TMVR</td>
<td>TAi / TF</td>
<td>preclinical</td>
</tr>
<tr>
<td>Neovasc</td>
<td>Tiara</td>
<td>TA / TF</td>
<td>clinical</td>
</tr>
<tr>
<td>Tendyne</td>
<td>Tendyne Lutter</td>
<td>TA</td>
<td>clinical</td>
</tr>
<tr>
<td>Twelve</td>
<td>TMVR</td>
<td>NA</td>
<td>IP</td>
</tr>
<tr>
<td>ValtechCardio</td>
<td>Cardiovalve</td>
<td>TF</td>
<td>preclinical</td>
</tr>
</tbody>
</table>
Percutaneous Valves
GDS Accucinch System

No Clinical Data Yet
CARILLON Device

Wire-form geometry of modified device designed to improve fatigue strength and device durability
Clinical Experience – First Two Studies

• AMADEUS\(^1\)
  - Feasibility study of CARILLON system.
  - 30 patients implanted with 6-month f/u.
  - Feasibility established with improvement in MR, functional status and quality of life.

• TITAN\(^2\)
  - Safety and efficacy trial w/ non-blinded, non-randomized comparison group.
  - 36 patients implanted with 2-year f/u.
  - Long-term improvements in MR, functional status, QoL and reverse remodeling observed.

What is the Evidence for MitraClip

- Which patients
  - Degenerative versus functional MR
  - Average versus high risk patients
- Which anatomy (lesion) is treatable
- Safety
  - Mortality, stroke, need for operation
- Efficacy
  - Mortality
  - QOL, MR reduction, LV remodeling, Hospitalization
MitraClip

The Delivery System

Catheter-based Delivery
Septal crossing
Case 1

90 year old patient with prior CABG 2002, now with CHF
3 admissions in 3 months, mother of a surgeon
4++ MR and normal LV, PHTN with RVSP 70 mm Hg
Cr 1.8, no recent cath, no CP
Severe MAC with MVA 3.5 cm$^2$
Mechanism appears to anterior flail
Confirm Flail on TEE

Flail Gap 3 mm And Flail Width 4 mm
Does this apply?  
Degenerative Mitral Valve Disease: 10 year Outcome

18% above age 70, none above 90 and redo
MV Surgery: Impact of Age and Comorbidities

- Older age is associated to:
  - Higher mortality (x3)
  - More stroke (x3)
  - Higher morbidity (x3)
  - Longer LOS (x1.5)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>&lt; 50 yrs</th>
<th>50-59 yrs</th>
<th>60-69 yrs</th>
<th>70-79 yrs</th>
<th>≥ 80 yrs</th>
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<tbody>
<tr>
<td>Sample Size</td>
<td>4315</td>
<td>5037</td>
<td>8472</td>
<td>11144</td>
<td>2720</td>
</tr>
<tr>
<td>Complications (%)</td>
<td>13.51</td>
<td>17.79</td>
<td>23.11</td>
<td>29.47</td>
<td>35.48</td>
</tr>
<tr>
<td>Permanent stroke (%)</td>
<td>1.23</td>
<td>1.79</td>
<td>2.70</td>
<td>4.16</td>
<td>4.52</td>
</tr>
<tr>
<td>Reoperation for bleeding (%)</td>
<td>3.75</td>
<td>4.61</td>
<td>5.21</td>
<td>6.74</td>
<td>8.53</td>
</tr>
<tr>
<td>Renal failure (%)</td>
<td>3.87</td>
<td>5.74</td>
<td>8.23</td>
<td>11.28</td>
<td>15.22</td>
</tr>
<tr>
<td>Deep sternal wound infection (%)</td>
<td>0.44</td>
<td>0.75</td>
<td>0.74</td>
<td>0.68</td>
<td>0.51</td>
</tr>
<tr>
<td>Length of stay (d)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>11.43 (12.23)</td>
<td>12.36 (13.52)</td>
<td>13.32 (13.20)</td>
<td>15.18 (14.66)</td>
<td>16.31 (14.13)</td>
</tr>
<tr>
<td>Postoperative length of stay (d)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>8.71 (9.74)</td>
<td>9.69 (11.04)</td>
<td>10.58 (11.37)</td>
<td>12.21 (13.11)</td>
<td>13.22 (13.17)</td>
</tr>
<tr>
<td>Operative mortality (%)</td>
<td>4.08</td>
<td>5.46</td>
<td>7.91</td>
<td>12.19</td>
<td>16.99</td>
</tr>
</tbody>
</table>

Procedure
Clip Insertion
Result – 2+ MR (from 4 ++ MR)
Hemodynamics
Do we need data for these patients?

- Clearly no randomized data
- However, FDA approved the clip for these patients
- We will not have randomized data for prohibitive risk degenerative patients against “standard” therapy
Another Patient

- 84 year old gentleman with DM, DCM, COPD (FEV1=0.8)
- s/p BiV pacing
- Cath with mod CAD – 40% LAD, 60% Dg, 40% RCA
- PAP = 50/20 mm Hg, CO = 5 L/min
- EF 22%, 3-4+ MR (ROA = 0.38 cm²)
- STS Score = 20.7
STS Score

- 84 year old
- DM, insulin
- EF 25%
- Single vessel CAD
- h/o Stroke
- Cr = 1.5 mg/dl
- Class IV
- Severe lung disease
- Inotropes (intermittent)

<table>
<thead>
<tr>
<th>Calculations</th>
<th></th>
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<tbody>
<tr>
<td>Procedure Name</td>
<td>Isolated MVRepr</td>
</tr>
<tr>
<td>Risk of Mortality</td>
<td>20.7%</td>
</tr>
<tr>
<td>Morbidity or Mortality</td>
<td>67.0%</td>
</tr>
<tr>
<td>Long Length of Stay</td>
<td>53.8%</td>
</tr>
<tr>
<td>Short Length of Stay</td>
<td>2.3%</td>
</tr>
<tr>
<td>Permanent Stroke</td>
<td>3.6%</td>
</tr>
<tr>
<td>Prolonged Ventilation</td>
<td>66.6%</td>
</tr>
<tr>
<td>DSW Infection</td>
<td>2.1%</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>29.6%</td>
</tr>
<tr>
<td>Reoperation</td>
<td>21.8%</td>
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</table>
Transthoracic Echocardiogram
LV Size: Before Procedure
Baseline TEE
Severity of MR
Major medical Society practice guidelines do not support MV surgery in the proposed patient population

<table>
<thead>
<tr>
<th>Heart Failure Guidelines</th>
<th>ACC/AHA</th>
<th>The effectiveness of mitral valve repair or replacement is not established for severe secondary mitral regurgitation in refractory end-stage HF. &lt;br&gt; <em>Class of recommendation IIb, level of evidence C</em></th>
</tr>
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<tbody>
<tr>
<td>ACC/AHA</td>
<td>HFSA</td>
<td>Isolated mitral valve repair or replacement for severe mitral regurgitation secondary to ventricular dilatation in the presence of severe left ventricular systolic dysfunction is not generally recommended &lt;br&gt; <em>Class of recommendation IIb, level of evidence C</em></td>
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<tr>
<td>ESC</td>
<td>ESC</td>
<td>Surgery may be considered in selected patients with severe functional MR and severely depressed LV function, who remain symptomatic despite optimal medical therapy. &lt;br&gt; <em>Class of recommendation IIb, level of evidence C</em></td>
</tr>
<tr>
<td>ISHLT</td>
<td>ISHLT</td>
<td>MV repair may be considered for patients with chronic severe secondary MR due to severe LV dysfunction (LVEF &lt; 30%) who have persistent NYHA functional class III–IV symptoms despite optimal therapy for heart failure, including biventricular pacing. &lt;br&gt; <em>Class of recommendation IIb, level of evidence C</em></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Patients with severe MR, LVEF .30%, no option for revascularization, refractory to medical therapy, and low comorbidity. &lt;br&gt; <em>Class of recommendation IIb, level of evidence C</em></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>In patients with heart failure and low LVEF, ventricular restoration surgery or mitral valve repair may be considered &lt;br&gt; <em>Class of recommendation IIb, level of evidence C</em></td>
</tr>
</tbody>
</table>

Cleveland Clinic c/o Dr. Patrick McCarthy
Survival After CABG Repair of Functional MR

CABG alone

CABG + MV anuloplasty

Survival

Years

Cleveland Clinic

Mihaljevic et al, J Am Coll Cardiol 2007;49:2191–201
# Mortality

<table>
<thead>
<tr>
<th>Study name</th>
<th>Dead / Total</th>
<th>Risk ratio and 95% CI</th>
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<tbody>
<tr>
<td></td>
<td>Mitral surgery</td>
<td>CABG alone</td>
</tr>
<tr>
<td>Harris et al. [5]</td>
<td>17 / 34</td>
<td>69 / 142</td>
</tr>
<tr>
<td>Trichon et al. [11]</td>
<td>87 / 228</td>
<td>243 / 687</td>
</tr>
<tr>
<td>Diodato et al. [12]</td>
<td>22 / 51</td>
<td>18 / 51</td>
</tr>
<tr>
<td>Wong et al. [7]</td>
<td>13 / 31</td>
<td>83 / 220</td>
</tr>
<tr>
<td>Kim et al. [10]</td>
<td>77 / 187</td>
<td>61 / 168</td>
</tr>
<tr>
<td>Buja et al. [9]</td>
<td>12 / 39</td>
<td>22 / 50</td>
</tr>
<tr>
<td>Bonacchi et al. [8]</td>
<td>10 / 54</td>
<td>14 / 40</td>
</tr>
<tr>
<td>Mihaljevic et al. [13]</td>
<td>92 / 290</td>
<td>37 / 100</td>
</tr>
</tbody>
</table>

Favours MVS       Favours CABG alone
4-Year Results of a Randomized Controlled Trial of Percutaneous Repair Versus Surgery for Mitral Regurgitation

Laura Mauri, MD, et al. for the EVEREST II Investigators

JACC 2013;62:317-28

Survival

MV surgery-free survival

Days Post Index Procedure

Device Group (n=178)

Control Group (N=80)
COAPT: Trial design

- Significant FMR (≥3+ by core lab)
- Not appropriate for mitral valve surgery
- Specific anatomical criteria

MitraClip
N=210

Control group
Standard of care
N=210

Clinical and TTE follow-up:
1, 6, 12, 18, 24, 36, 48, 60 months
Unmet Need: Cleveland Clinic Database

Echo Database Queried for ≥ 3+ MR
EMR Queried using ICD-9 codes for Heart Failure
CPT codes to identify those undergoing MV surgery

1,095 patients with severe symptomatic MR

577 (53%) No MV surgery
518 (47%) MV surgery

520 (90%) FMR
36 (6%) DMR
294 (57%) FMR
190 (37%) DMR

Goel et al, JACC 2013
Advancing the Clip
First Clip
Clip Orientation
Placing Clip – Leaflet insertion, Closing
MR after 1\textsuperscript{st} Clip
Second Clip: Positioning
Second Clip Orientation
Advancing Through MV
Capture of Leaflet
Closing the Second Clip
Second Clip Closure
LV Function
Mitral Stenosis (?)
Mitral Gradient After Clips

First Clip

Second Clip
Two Clips
Final Result
Follow-up Echo: MR at 6 months
LV Function
6 Months After Procedure
# Measurements: Before and After

<table>
<thead>
<tr>
<th>Before</th>
<th>After</th>
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<tbody>
<tr>
<td>EDV = 235 ml</td>
<td>EDV = 218 ml</td>
</tr>
<tr>
<td>ESV = 180 ml</td>
<td>ESV = 169 ml</td>
</tr>
<tr>
<td>EDD = 6.5 cm</td>
<td>EDD = 6.5 cm</td>
</tr>
<tr>
<td>ESD = 6.1 cm</td>
<td>ESD = 5.8 cm</td>
</tr>
<tr>
<td>EF = 23%</td>
<td>EF = 23%</td>
</tr>
<tr>
<td>Mean MVG = 1</td>
<td>Mean MVG = 2</td>
</tr>
<tr>
<td>RVSP = 40</td>
<td>RVSP = 25</td>
</tr>
<tr>
<td>LAA = 38</td>
<td>LAA = 41</td>
</tr>
<tr>
<td>LAD = 7.8</td>
<td>LAD = 7.9</td>
</tr>
<tr>
<td>NYHA = 4</td>
<td>NYHA = 2</td>
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</table>
Summary

- Percutaneous treatment of MR is a reality.
- Inoperable patients with Degenerative MR can be treated with MitraClip today.
- Symptomatic patients with functional MR who are not considered for surgery should be considered for COAPT trial.
- Newer percutaneous therapies will expand options for larger patient population of mainly Functional MR.
- Exciting times the ahead of us for mitral therapies!
Aortic Stenosis

- 75 year old patient
- No prior cardiac history
- Presents with shortness of breath with exertion
- No CP
- No lightheadedness
- O/E BP 120/80, HR 90
- No JVD
- S1 normal A2 not heard, late peaking systolic murmur
- No edema
- Lungs clear
Echocardiography
Sternotomy

Courtesy Dr. Mick
Aorta Cross-clamped
Surgical Aortic Valve Replacement

Courtesy of Dr. Gosta Pettersson
Surgical AVR
Clinical Presentation

- 80 yr old, male  Ht:171.5cm  Wt: 70.1kg  BMI: 23
- NYHC III
- HTN, CAD, A fib
- S/P Hemashield Graft/ Bentall- 1999
  (Ascending Aortic Aneurysm)
- S/P AVR #25 CE 1999
- S/P Arch Repair 2010
- Complicated post op recovery
  encephalopathy, suicidal/paranoid ideation
- Former Smoker- Quit 1973
- Hb:12.3  Ht: 37.1
- FEVI: 3.09 (119%)  DLCO: 24.5(107%)
Cardiologist – Surgeon Collaboration

- Co-leadership
- Continuous and open communication
- Early conflict resolution
- Consensus building
- Shared resources
- Shared credits
- Great facility
Setup
Access

8F IMA guide

0.018" (V18) wire
Typical Access

RFA - 8 F Sheath
Pigtail and contralateral wire

RFV - 5 F Sheath
For CPS

LFV - 5 F Sheath
Temp Pacemaker

LFA - Valve Access Sheath
Sheath Insertion
Setup of Camera

RAO Caudal

LAO Cranial
Hemodynamics
Inserting the Wire
Valve Preparation
Valve Preparation
Loading of Sapien XT
Fine Adjusting
Crossing the Arch
Uncovering the Balloon
Positioning
Positioning by Echo

With Pacing
Deployment
Deployment
Hemodynamics
Final Result
Hurdles

Complications

Paravalvular leak
Stroke
Heart block
Vascular
Coronary occlusion

Economics
Durability
Newer Valve Designs - S3
Newer Valve Design – Direct Flow
When We See it Coming – What do we do in Cleveland?

RICA EPD
LICA EPD
RSCA Balloon
LSCA Balloon
How to Accomplish This – Just Work Hard!

- 8F IMA Guide w Crossover wire
- 5F RFV sheath
- 6F/80 Shuttle 5F LFV sheath w LICA Filter w TPM
- 6F/45 Shuttle w RSCA balloon
- 6F/80 Shuttle w RICA Filter
- 23F SAPIEN Delivery sheath
- 6F/45 Shuttle w LSCA balloon
Stroke Prevention Measures

- Emboli prevention devices
  - Claret device - Sentinel Trial
  - Embrella Device - ProTAVI
- Carotid pressure at the time of advancing the sheath
- Careful manipulations
- Minimize postdilations
- ? Pretreat carotid disease
Our Setup
Cleveland Clinic Experience

Single Center TAVR Experience With a Focus on the Prevention and Management of Catastrophic Complications

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Outcome of Patients TF-TAVR at Cleveland Clinic

<table>
<thead>
<tr>
<th>Year</th>
<th>Major Stroke</th>
<th>Total Procedure</th>
<th>Major Bleeding</th>
<th>Total Procedure</th>
<th>Vascular Complications</th>
<th>Total Procedure</th>
<th>30-Day Mortality</th>
<th>Total Procedure</th>
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<tr>
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<td>92</td>
<td>7</td>
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</tr>
</tbody>
</table>

30-day mortality (0.4%)

Stroke (2.0%)

Major bleeding (5.2%)

Vascular Complications (9.6%)
30 Day Mortality with TF-TAVR

- GERMANY*, n=833: 12.4%
- FRANCE, n=2107: 9.6%
- ITALY*, n=663: 5.4%
- PARTNER B, n=179: 5%
- PARTNER A, n=244: 3.3%
- Cleveland Clinic, n=255: 0.4%

* Includes TF and TA, all others TF or
1 Year Mortality with TF-TAVR

- PARTNER B, n=179: 30.7%
- FRANCE, n=2107: 24%
- PARTNER A, n=244: 22.2%
- ITALY*, n=663: 15%
- Cleveland Clinic, n=255: 14%

* Includes TF and TA, all others TF only
Paravalvular Leak Closure
Clinical History

- 73 year old man
- Complained of worsening fatigue and dyspnea
- Past Medical History:
  - Mitral valve replacement (CE #33)
  - Hypertension
  - Hyperlipidemia
  - Atrial fibrillation
  - COPD (severe by PFTs)
Mitral Paravalvular Leak (PVL)

Parasternal long axis  Apical 4-chamber
Preprocedural TEE – PVL localization

MV viewed from the ventricle
Procedural Decisions

• **Diagnosis:**
  - Moderate/severe mitral paravalvular leak (PVL)
  - Medial origin (1-2 o’clock)

• **Plan:**
  - Percutaneous PVL closure
  - Posterior and inferior transseptal puncture
Intracardiac Echo – PVL localization
Wiring the PVL
Advancing Delivery Sheath

LA
LV
RA
TEE Probe Inserted
Deploying Amplatzer Vascular Plug

RAO Projection

LAO projection

LA
LV
Device in Place
ICE Confirms PVL Closure

Pre-PVL Closure  Post-PVL Closure
TEE Confirms PVL Closure