Para-valvular Leak Closure

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Athens, Greece
Disclosures

I and the HYGEIA Hospital «Heart Team» have received research and travel grants from: Medtronic, St Jude, Europe, ABBOTT Vascular, Europe

HYGEIA Hospital Heart Team

Cardiologists: A Tzifa, A Halapas, M Chrissoheris, K Spargias
CT Surgeons: N Boumboulis, S Skardoutsos, A Tsolakis, S Pattakos
Anesthesiologist: I Nikolaou
Vascular Surgeons: I Bellos, S Kaliafas
Radiologists: C Mourmouris, F Laspas
Para-valvular Leak - PVL

• More common with Mitral than Aortic valve replacements
  – 2–10 % of patients with an aortic valve replacement
  – 7–17 % with a mitral valve replacement

• More common with Mechanical than Biological valve replacements

• More common with Stented than Stent-less Bio-prosthesis

Aortic PVL

- Less frequent (1-5%) than MV (2-12%)
- Symptoms less frequent than MV
  - Hemolysis less frequent than MV
    - Smaller pressure gradients
- More commonly located between the right and non-coronary cusps
- Para-AV defects smaller than para-MV defects
  - Usually closed with a single device
- No gradient across the leak during systole but during diastole
- Risk of ventricular embolization

Mitral PVL

- Mitral valve PVL repair is more complex than aortic PVL repair
- Most often located
Pathogenesis - etiology

• PVLs are due to incomplete apposition of the sewing ring to the native tissue

• **Early** occurrence of PVLs
  
  – Associated with the technical aspects and more commonly with MVR
    
    • Result of either suture knot failure, inadequate suture placement, or separation of sutures from a pathologic annulus

• **Late** occurrence of PVLs
  
  – Clinical, anatomical and technical factors increase the risk of PVL formation

Shape of PVLs

Most reported leaks are either oval- or crescent shaped accounting for 80-85% of the cases with irregular borders.
Clinical presentation

- Most PVLs are asymptomatic with benign clinical course

- An estimated 1–5% of pts with PVLs can lead to clinical consequences:
  
  - Congestive heart failure in ~90% of cases
    
    - Volume overload due to Large Leaks - having a mean NYHA functional class of ≥ III
  
  - Symptomatic hemolysis ranging from 1/3 - 3/4 of cases
    
    - Small Leaks / Mitral Position
  
  - Infectious endocarditis in 15%

Paul Sorajja et al. Am Coll Cardiol 2011;58: 2218–24
Influence of therapeutic strategy on survival

Indications for treatment

• The recommended approach has been surgical closure especially in patients with:
  – Infectious endocarditis
  – With a need for concurrent coronary bypass
  – With associated mechanical instability of the prosthesis.

• However, surgical repair (Re-operation) usually associated with:
  – Significant morbidity and mortality than increases progressively
    • 13% after the 1st, 17% after the 2nd and 37% after the 3rd
  – May not be successful since the original anatomical problems persist
    • High recurrence of PVL may be seen in more than 1/3 of pts who undergo redo OHS for PVL

CLASS IIa

Percutaneous repair of PVLs is reasonable in pts with prosthetic heart valves and intractable hemolysis or NYHA class III/IV HF who:

• Are at high risk for surgery
• Have anatomic features suitable for catheter-based therapy
• Performed in centers with expertise in the procedure
Which PVL is appropriate for Percutaneous closure?

Anatomic features suitable for catheter-based therapy

Favorable

• > 3mm distance from sewing ring to defect
• Small in size
• Single
• Short tunnel
Percutaneous PVLs closure

limitations

• Mechanical instability of prosthetic valve
  – Rocking valve

• The presence of thrombus

• Calcified inter-atrial septum

• The active endocarditis or systemic infection

• Need for coronary bypass surgery
Complications

- Obstruction of mechanical tilting-disk
- Coronary artery obstruction
  - With para-aortic PVLs because devices may protrude over the ostia of coronary arteries
- Cardiac perforation – tamponed
- Embolization of the occluder devices - reported in <1 % to 5 % of large series
- Stroke or TIA
  - May result from systemic thromboembolism
- Hemothoraces - after Trans-apical approach
- Vascular injury after Trans-femoral approach
- Procedural death <0.5%

PVL and RT-3D TEE

• The gold standard diagnostic method
  – Sensitive enough to detect small paravalvular leaks of 3 mm

• It is very useful to define the:
  – Location, orientation (use common orientation)
  – Shape, size
  – Severity, especially mitral PVLs (multi-parametric)
    • jet of width, number of PVLs, circumferential extent, PIISA, pulmonroar reversal

• During the procedure TEE confirms:
  – Correct functioning of the prosthetic valve
  – Correct positioning of the device
  – Degree of residual regurgitation

• Limitation
  – Dropout phenomenon secondary to an under-gained image, giving the impression of a false anatomic defect, leading to speculation of nonexistent pathology.
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PVL and ECG-gated CT

ECG-gated computed tomographic angiography (CTA) with 3D/4D-reconstruction using volume rendering techniques has become an increasingly utilized tool in PVL evaluation.

• This imaging modality assists in determining the exact:
  – Location
  – Shape
  – Size

• Limitation
  – Artifacts from dense structures such as prosthetic valves or extensive calcification may limit PVL size estimation.
  – Exposure to radiation and i.v. contrast media increases the risks associated with the procedure.
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Choice of Device

- **Amplatzer™ Vascular Plug II (AVP II)**, most often used, low profile, round shaped, consists of a nitinol cylinder with a nitinol disc on either side.

  The AVP I is a single cylinder design, making it less stable and effective.

  The AVP III is approved in Europe and Canada not available in the US.

- **Oval shaped** dense nitinol mesh and available dimensions of the AVP has the advantage of being better adapted to close oval or crescent-shaped leaks.

- **Atrial septal defect (ASD) occlusion devices** is often complicated by the large discs that can interfere with the prosthetic valve,

- **Ventricular septal defect (VSD) closure devices** are quite stiff and often result in worsening hemolysis.

Tuesday, March 10, 15
How to Cross?

Different approaches for PVL closure

Anterograde approach
Femoral vein and trans-septal puncture

Retrograde approach
from the femoral artery

Transapical approach

Mainly for treatment of Mitral PVL
Mainly for treatment of Aortic PVL
Mainly for treatment of Mitral PVL
Transcatheter Umbrella Closure of Valvular and Paravalvular Leaks

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Boston, Massachusetts

Objectives. Our aim was to adapt the technique of transcatheter umbrella closure of intracardiac defects for closure of valvular and paravalvular defects.

Background. The double-umbrella device developed by Rashkind and Cuaso has been safely and effectively delivered across a host of intracardiac defects, but transcatheter closure of valvular and paravalvular leaks has not been reported.

Methods. Between February 1987 and September 1990, eight patients who were believed to be poor operative candidates were taken to the catheterization laboratory for transcatheter double-umbrella closure of a valvular or a paravalvular leak. Four patients had a paravalvular leak around a prosthetic aortic valve. The other four patients had a valvular leak: one patient with a regurgitant native aortic valve after a Stansel procedure and three patients with a regurgitant porcine valve in a left ventricular apex to descending aorta conduit.

Results. Placement of a double-umbrella device was attempted in seven of the eight patients and was successful in all seven. Device placement was not attempted in one patient because of the crescentic shape of his defect. Two patients required two devices for each closure; the other five required only one device each. Angiography, performed on six patients after device closure, demonstrated that three patients had a completely occluded defect, two had trivial residual flow and one patient had mild residual flow through the device. All significant complications occurred in one patient who had hemolysis and oliguria that resolved when the initial umbrella was replaced by a larger device. In addition, two devices migrated to the patient’s pulmonary arteries but were retrieved in the catheterization laboratory without difficulty. No other early or late complications occurred in 21 to 50 months of follow-up. Of the four patients with a paravalvular leak, the one who did not receive a device died at operation, one patient died at operation for an associated defect (in the operating room the umbrella was found securely in place across the paraaortic defect) and two patients are clinically well at home after 21 and 32 months, respectively. Of the four patients with closure of a valvular leak, one patient remains well at home 50 months later, one patient died at operation for associated defects and two patients had additional successful surgical treatment and remain well 29 months after device placement.

Conclusions. Transcatheter umbrella closure appears to be a reasonable alternative for closure of a valvular or paravalvular leak in patients who are poor operative candidates.

(I Am Coll Cardiol 1992;20:1371-7)
## Transcatheter prosthetic paravalvular leak closure

<table>
<thead>
<tr>
<th>Studies</th>
<th>Years</th>
<th>Number of patients</th>
<th>Mitral leak</th>
<th>Aortic leak</th>
<th>Implantation success</th>
<th>Procedural success</th>
<th>30-day mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hourihan</td>
<td>1992</td>
<td>4</td>
<td>0</td>
<td>4</td>
<td>3/4 (75%)</td>
<td>2/3 (66.7%)</td>
<td>NA</td>
</tr>
<tr>
<td>Pate</td>
<td>2001–2004</td>
<td>10</td>
<td>9</td>
<td>1</td>
<td>4/10 (40%)</td>
<td>7/10 (70%)</td>
<td>0</td>
</tr>
<tr>
<td>Cortés</td>
<td>2003–2006</td>
<td>27</td>
<td>27</td>
<td>0</td>
<td>17/27 (62%)</td>
<td>8/17 (47%)</td>
<td>0</td>
</tr>
<tr>
<td>Shapira</td>
<td>2003–2006</td>
<td>11</td>
<td>10</td>
<td>3</td>
<td>10/11 (91%)</td>
<td>6/10 (60%)</td>
<td>0</td>
</tr>
<tr>
<td>Hein</td>
<td>2002–2006</td>
<td>21</td>
<td>13</td>
<td>8</td>
<td>20/21 (95%)</td>
<td>14/20 (70%)</td>
<td>2/21 (9.5%)</td>
</tr>
<tr>
<td>Sorajja</td>
<td>2004–2007</td>
<td>16 (19 P)</td>
<td>14</td>
<td>2</td>
<td>NA</td>
<td>17/19 (81%)</td>
<td>1/16 (6.2%)</td>
</tr>
<tr>
<td>Garcia</td>
<td>2003–2009</td>
<td>52</td>
<td>52</td>
<td>0</td>
<td>33/52 (63.5%)</td>
<td>17/33 (51.5%)</td>
<td>NA</td>
</tr>
<tr>
<td>Nietlispach</td>
<td>2009</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td>5/5 (100%)</td>
<td>5/5 (100%)</td>
<td>0</td>
</tr>
<tr>
<td>Sorajja</td>
<td>2004–2010</td>
<td>115 (141 P)</td>
<td>78%</td>
<td>22%</td>
<td>125/141 (88.6%)</td>
<td>77% M 75% A 80% Mec 71% Bio 84%</td>
<td>2/115 (1.7%)</td>
</tr>
<tr>
<td>Sorajja**</td>
<td>2004–2011</td>
<td>126 (154 P)</td>
<td>78.6%</td>
<td>21.4%</td>
<td>91.3%</td>
<td>76%</td>
<td>3/126 (2.4%) 64.3%*</td>
</tr>
<tr>
<td>Ruiz</td>
<td>2006–2010</td>
<td>43 (57 P)</td>
<td>76.8%</td>
<td>23.2%</td>
<td>86%</td>
<td>89%</td>
<td>2/43 (4.6%)</td>
</tr>
<tr>
<td>Montreal</td>
<td>2001–2010</td>
<td>56 (61 P)</td>
<td>79%</td>
<td>21%</td>
<td>75.4%</td>
<td>70.5% (43/61)</td>
<td>2/56 (3.6%)</td>
</tr>
</tbody>
</table>
Clinical Outcomes in Patients Undergoing Percutaneous Closure of Periprosthetic Paravalvular Leaks

- **Technical success** in 86% of cases
- **Clinical success** was 77%
  - improved by at least 1 NYHA
- **Pts requiring blood transfusions** decreased from 56% to 5%
- **Survival rate** at 6, 12, and 18m post PVL closures were 91.9%, 89.2%, & 86.5%, respectively
- **Freedom from cardiac-related death** at 42 months post-procedure was 91.9%

J Am Coll Cardiol 2011;58:2210–7
# Transcutaneous PVL Closure - Hygeia Hospital experience

<table>
<thead>
<tr>
<th>Patient (#)</th>
<th>Age (y)/Gender</th>
<th>MVR /AVR</th>
<th>Logistic Euro-Score (%)</th>
<th>CHF NYHA class</th>
<th>Hemolytic Anemia</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>60 / F</td>
<td>MVR + AVR</td>
<td>18.9</td>
<td>III-IV</td>
<td>YES</td>
</tr>
<tr>
<td>2</td>
<td>64 / M</td>
<td>AVR</td>
<td>12.6</td>
<td>II-III</td>
<td>NO</td>
</tr>
<tr>
<td>3</td>
<td>48 / M</td>
<td>AVR</td>
<td>37</td>
<td>III</td>
<td>YES</td>
</tr>
<tr>
<td>4</td>
<td>71 / M</td>
<td>MVR</td>
<td>48.6</td>
<td>IV</td>
<td>YES</td>
</tr>
<tr>
<td>5</td>
<td>75 / F</td>
<td>MVR + AVR</td>
<td>26.6</td>
<td>III-IV</td>
<td>YES</td>
</tr>
<tr>
<td>6</td>
<td>70 / M</td>
<td>MVR + AVR</td>
<td>23.4</td>
<td>III-IV</td>
<td>YES</td>
</tr>
<tr>
<td>7</td>
<td>74 / M</td>
<td>MVR + AVR</td>
<td>28.5</td>
<td>III</td>
<td>NO</td>
</tr>
<tr>
<td>8</td>
<td>75 / M</td>
<td>AVR</td>
<td>15.6</td>
<td>II-III</td>
<td>NO</td>
</tr>
</tbody>
</table>

**MEAN** | **67y / 75%M** | **62.5% MVR** | **26.4** | **3.2** | **62.5%YES**
# Transcutaneous Paravalvular Leak Closure
## Hygeia Hospital experience

<table>
<thead>
<tr>
<th>Patient (#)</th>
<th>Valve type</th>
<th>Valve size (mm)</th>
<th>Valve age (y)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>St. Jude</td>
<td>23</td>
<td>19</td>
</tr>
<tr>
<td>2</td>
<td>On-X</td>
<td>25</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>St. Jude</td>
<td>21</td>
<td>1/2</td>
</tr>
<tr>
<td>4</td>
<td>Carbomedics</td>
<td>25</td>
<td>14</td>
</tr>
<tr>
<td>5</td>
<td>ATS</td>
<td>31</td>
<td>7</td>
</tr>
<tr>
<td>6</td>
<td>Sorin Bicarbon</td>
<td>25</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>Epic</td>
<td>27</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>ATS</td>
<td>24</td>
<td>1</td>
</tr>
</tbody>
</table>
### Transcutaneous Paravalvular Leak Closure

**Hygeia Hospital experience**

<table>
<thead>
<tr>
<th>PROCEDURAL CHARACTERISTICS</th>
<th>HYGEIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUCCESSFULL IMPANTATION</td>
<td>100 %</td>
</tr>
<tr>
<td>NUMBER OF DEVICES DEPLOYED: 1 / 2 / 3</td>
<td>62.5 / 25 / 12.5 %</td>
</tr>
<tr>
<td>PVL OCCLUDER: ADO / AVP II / AVP III</td>
<td>54.5 / 18.3 / 27.2</td>
</tr>
<tr>
<td>FLUOROSCOPY TIME (mean)</td>
<td>0:33:50min</td>
</tr>
<tr>
<td>ICU (mean)/ TOTAL HOSPITAL STAY (mean)</td>
<td>38h / 5.4d</td>
</tr>
</tbody>
</table>
Patient Characteristics

- 70 year-old male, rheumatic heart disease
- 1967: Closed mitral Valvotomy
- 1990: Surgical mitral and aortic valve replacement (St. Jude 21mm)
- 2010: *Redo MVR (Sorin Bicarbon 25mm)* & TR repair (Cosgrove-Edwards)
  - NYHA III - multiple admittions for drainage of Right pleural effusion
  - Severe hemolytic anemia - frequent transfusions
- Chronic Atrial Fibrillation, severe Pulmonary Hypertension
- Chronic lung disease, Diabetes mellitus type 2
Baseline Mitral Valve and 3D Color

Medially located PVL with severe MR
Baseline Mitral Valve and 3D Color

Medially located PVL with severe MR
Baseline Mitral Valve and 3D Color

Medially located PVL with severe MR
Medial PVL

Sizing using Vena Contracta Area

- Crescent shape
- Vena Contracta 8x2mm
Transapical Access

Exposure of cardiac apex, purse string sutures, insertion of an 8F sheath into left ventricular cavity
Access via PVL space

Diagnostic Multipurpose Catheter 6F
Terumo hydrophylic wire
Access via PVL space

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Terumo hydrophylic wire
Access via PVL space

Diagnostic Multipurpose Catheter 6F
Terumo hydrophylic wire
Amplatzer Duct Occluder

With the use of Torque V (45° 7F) sheath a device
ADO 12/10 was successfully placed in the area of PVL
Amplatzer Duct Occluder

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Amplatzer Duct Occluder

With the use of Torque V (45° 7F) sheath a device
ADO 12/10 was successfully placed in the area of PVL
Final Result
Final Result
Final Result
• **Transapical access** offers direct approach to MV PVLs
  
  Alternative to AV wire loop techniques especially in patients with mechanical aortic valve as well

• **ADO via transapical approach**
  
  less likely to interact with mechanical valve
Patient Characteristics

• 76 year-old male

• **2012:** Surgical AVR and CABG (SVG → LAD)

• **01-2014:** Sub-acute IE

• **03-2014:** inferior lateral STEMI

• **2014 - Redo AVR (ATS 24mm) & CABG (SVG → RCA)**

• **NYHA III** - multiple admissions for drainage of Right pleural effusion

• **Chronic atrial fibrillation**
Baseline echo

Baseline aortography
Baseline echo

Baseline aortography
Baseline RT 3D - TEE

03-07-2014

Aortic Para-valvular Leak

characteristics:

• Crescend in shape
• Located near to non-coronary sinus
• Dimensions 7 x 3 mm

LVEF 55%

EDD 63mm

MR 2+

TR 2+

PAPs 50mmHg
Baseline RT 3D - TEE
03-07-2014

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03-07-2014

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PAPs 50mmHg
Trans-Femoral Access

Right Femoral artery with 10F sheath
Trans-Femoral Access

Right Femoral artery with 10F sheath
Trans-Femoral Access

Right Femoral artery with 10F sheath
Diagnostic Multipurpose Catheter 6F,

Terumo hydrophylic wire and then amplatz extra stiff wire
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Terumo hydrophylic wire and then amplatz extra stiff wire
Amplatzer™ Vascular Plug II
12/9mm

With the use of Torque V 5F sheath a device AVP II 12/19mm was placed in the area of PVL

Obstruction of mechanical tilting-disk
Amplatzer™ Vascular Plug II

12/9mm

With the use of Torque V 5F sheath a device AVP II 12/19mm was placed in the area of PVL

Obstruction of mechanical tilting-disk
Amplatzer™ Vascular Plug III
10/5mm

With the use of Torque V (5F) sheath a device AVP III 10/5 was placed in the area of PVL however small in size
Amplatzer™ Vascular Plug III
10/5mm

With the use of Torque V (5F) sheath a device AVP III 10/5 was placed in the area of PVL however small in size
Amplatzer™ Vascular Plug III
10/5mm

With the use of Torque V (5F) sheath a device AVP III 10/5 was placed in the area of PVL however small in size.
Amplatzer™ Vascular Plug II

10/7mm

With the use of Torque V (5F) sheath a device AVP II 10/7 was successfully placed in the area of PVL
With the use of Torque V (5F) sheath a device AVP II 10/7 was successfully placed in the area of PVL.
Amplatzer™ Vascular Plug II

10/7mm

With the use of Torque V (5F) sheath a device AVP II 10/7 was successfully placed in the area of PVL.
Amplatzer™ Vascular Plug II

10/7mm

With the use of Torque V (5F) sheath a device AVP II 10/7 was successfully placed in the area of PVL
Final Result

Baseline

Final

Significant improvement in degree of aortic PVL
Final Result

Baseline

Final

Significant improvement in degree of aortic PVL
Procedure challenges

• Various size and shape of defect

• No specific device

• Imaging is key but difficult
Conclusion

• RT 3D TEE is critical in identifying location and characteristics of PVL

• Integration of MDCT and 3D-ECHO data with fluoroscopy may further expedite access to PVLs
Conclusion

Due to the complexity of these procedures, consideration should be given to their performance in centers of expertise under the guidance of a multidisciplinary Heart Team.
4ο Συνέδριο
Διακαθετριακής Θεραπείας
Δομικών Καρδιοπαθείων
& Προσυνεδριακό Σεμινάριο
Ειδικευόμενων και Νέων
Καρδιολόγων

14 - 16/05/2015
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ΜΗΤΕΡΑ, Αθήνα

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