Para-valvular Leak Closure

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Vascular Surgeons: I Bellos, S Kaliafas

Radiologists: C Mourmouris, F Laspas
Para-valvular Leak - PVL

• More common with Mitral than Aortic valve replacements
  – The reported cases involved
    • Mitral PVLs → 7 - 17%
    • Aortic PVLs → 2 – 10%

• 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%) PVLs
- **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
  - Ao pressure > LV pressure

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 $\rightarrow$ 60% of cases
  
  – 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
Long-Term Outcomes of Percutaneous Paravalvular Regurgitation Closure After Transcatheter Aortic Valve Replacement
A Multicenter Experience

Francesco Saia, MD, PhD,* Claudia Martinez, MD,† Sameer Gafoor, MD,† Vikas Singh, MD,† Cristina Ciucă, MD,* Ilona Hofmann, MD,‡ Cinzia Marrozzini, MD,* John Tan, MD,§ John Webb, MD,§ Horst Sievert, MD, PhD,¶ Antonio Marzocchi, MD,* William W. O’Neill, MD}
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 93% of cases
    
    • Volume overload due to **Large Leaks** - having a mean NYHA functional class of ≥ III

  – Symptomatic hemolysis 37% of cases
    
    • Sub-clinical hemolysis observed in almost 50%
    
    • **Small Leaks** - The degree of hemolysis does not correspond to the degree of PVL
    
    • **Mitral Position** + More common with Mechanical

  – **Infectious endocarditis** in 7.5%

Paul Sorajja et al. Am Coll Cardiol 2011;58: 2218–24
Mechanisms of Hemolysis With Mitral Prosthetic Regurgitation
Study Using Transesophageal Echocardiography and Fluid Dynamic Simulation

MARIO J. GARCIA, MD, PIETER VANDERVOORT, MD, WILLIAM J. STEWART, MD, FACC, BRUCE W. LYTLE, MD, FACC, DELOS M. COSGROVE III, MD, FACC, JAMES D. THOMAS, MD, FACC, BRIAN P. GRIFFIN, MD, FACC
Cleveland, Ohio

Hemodynamic Patterns of regurgitant flow with & without hemolysis

**with hemolysis**

**Fragmentation**
Regurgitant jet is divided by a dehisced annular support ring

**Collision**
PVL regurgitant jet is suddenly decelerated when colliding with the left atrial appendage wall

**Uncelaration**
Jet is seen traversing through a small perforation in a thickened degenerated bioprosthesis

**without hemolysis**

**Free jet**
Central jet travels through a large orifice in a bioprosthesis with a torn cusp

**Deceleration**
Large PVL mitral regurgitation jet slides gently along the atrial wall.
Influence of therapeutic strategy on survival

![Graph showing the influence of surgical and conservative strategies on patient survival over 8 years, with a p-value of 0.035.]
**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 1\(^{st}\), 17% after the 2\(^{nd}\) and 37% after the 3\(^{rd}\)
  - 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

Level of Evidence B
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%

Abstract

Paravalvular leak is a common complication after surgical mitral valve replacement. Surgically implanted prosthetic valves are complicated with paravalvular leaks in 17%. Surgical closure of paravalvular leaks is the most common therapy for these defects. Percutaneous closure is an alternative to repeat surgery for a selected high-risk population. We present a case of a patient who developed severe haemolytic anaemia and secondary renal failure after partially successful percutaneous closure of paravalvular leakage of a prosthetic mitral valve. The assumption is that the combination of a metallic foreign body and high shear stress caused haemolysis by damaging red blood cells.

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 reverasl

• 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.
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.
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.

- **Patent ductus arteriosus (PDA) occluders** are available in limited sizes, self-expanding device, made from Nitinol wire mesh.
  
  - Helpful when the AVP II discs interfere with valve leaflet motion
**Novel Occlutech VP Occluder**

2014, European **CE Mark** approval for its dedicated PVL Closure Device

Made of **nitinol** → giving flexibility and adaptability with a high success rate in achieving complete closure

**Square and rectangular-shaped**

**Security** mechanism

The device is available in different **sizes ranging** from 3 to 7 mm with a circular waist for the square device that requires 5-7 Fr sheaths and from 4×2 to 12×5 mm with an ellipsoid waist for the rectangular device that requires 5-8 Fr sheaths for delivery

Both designs are available for **transapical or endovascular delivery**
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 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>
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<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>
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<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>
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<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>
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<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>
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<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>
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<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>
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<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>
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<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>
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<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%</td>
<td>2/115 (1.7%)</td>
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<td></td>
<td></td>
<td></td>
<td>90 pts</td>
<td>25 pts</td>
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<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>
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<td>99 pts</td>
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<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>
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<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%</td>
<td>2/56 (3.6%)</td>
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<td></td>
<td>44 pts</td>
<td>12 pts</td>
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</table>

Cardiovascular Medicine 2012;15(9):245–252
Learning Curve

Sorajja et al. JACC 2011
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 → 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
Systematic Review/Meta-analysis

Transcatheter Reduction of Paravalvular Leaks: A Systematic Review and Meta-analysis

Technical success rates

- Mitral Procedures: 82.3%
- Aortic Procedures: 84.1%

Procedural success rates

- Mitral Procedures: 73.7%
- Aortic Procedures: 73.7%
The most frequently device was Amplatzer Vascular Plug in 80%.

- 88.9% of procedures were technically successful.
- The results assessed by echocardiography were durable.
- Survival rates at 1, 6, and 12 months were 83.3, 66.7, & 61.5%.
  - Most of the deaths were due to non-cardiac causes.
## Transcutaneous PVL Closure

### Hygeia Hospital Heart Team 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>
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<tr>
<td>1</td>
<td>60 / F</td>
<td>MVR + AVR</td>
<td>18.9</td>
<td>III-IV</td>
<td>YES</td>
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<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>
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<tr>
<td>8</td>
<td>75 / M</td>
<td>AVR</td>
<td>15.6</td>
<td>II-III</td>
<td>NO</td>
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<tr>
<td>9</td>
<td>81 / M</td>
<td>AVR</td>
<td>21</td>
<td>III</td>
<td>NO</td>
</tr>
<tr>
<td>10</td>
<td>61 / M</td>
<td>AVR</td>
<td>13.5</td>
<td>III-IV</td>
<td>NO</td>
</tr>
<tr>
<td>11</td>
<td>71 / M</td>
<td>MVR</td>
<td>23</td>
<td>III</td>
<td>NO</td>
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<tr>
<td><strong>MEAN</strong></td>
<td><strong>68y / 80%M</strong></td>
<td><strong>54.5% MVR</strong></td>
<td><strong>24.4</strong></td>
<td><strong>3.2</strong></td>
<td><strong>45.4%YES</strong></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>SUCCESFULL IMPANTATION</td>
<td>91 %</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 / Occlutech VP</td>
<td>51/20 /20/9 %</td>
</tr>
<tr>
<td>FLUOROSCOPY TIME (mean)</td>
<td>0:33:50 min</td>
</tr>
<tr>
<td>ICU (mean)/ TOTAL HOSPITAL STAY (mean)</td>
<td>38h / 5.4 d</td>
</tr>
</tbody>
</table>
Patient Characteristics

- 75 year-old male

- **2012**: Surgical AVR and CABG (SVG $\rightarrow$ LAD)

- **01-2014**: IE

- **03-2014**: inferior STEMI

- **2014**: Redo AVR (ATS 24mm) & CABG (SVG $\rightarrow$ RCA)

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

- Chronic atrial fibrillation
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
Diagnostic Multipurpose Catheter 6F,

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

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
Take Home message

PVL cases are **rare** and experience **scant**

**Combined** Heart Team experience

Meticulous clinical and **imaging screening**

Procedure can be **challenging** however **success rate is high**
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**.