Percutaneous VSD closure: Problems in the mid- and long-term

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What post-procedural complications occur?

- Residual shunt
- Interference with AV or semilunar valve function
- Arrhythmias...particularly cAVB
- Embolization
- Hemolysis

What factor(s) influence adverse post-procedural events?

- Anatomical
- Patient selection (age, weight, hemodynamics)
- Device (design, materials)
Perimembranous defects - anatomical considerations

- Location
  - Under chordae of TV
  - Rim between Ao V and defect can be non-existent
  - Bundle branch and AV node are near the defect rim
- Size of the defect
- Septal wall thickness
- Aneurysms
Perimembranous defects - complications

- Complete atrioventricular block (cAVB)
  - Early or late
  - Transient or permanent
  - Acute treatment options:
    - Abort procedure
    - Corticosteroids
    - Permanent pacemaker
Perimembranous defects - complications

• Complete atrioventricular block
  – Early or late
  – Transient or permanent
  – Acute treatment options:
    • Abort procedure
    • Corticosteroids
    • Permanent pacemaker

• Aortic or tricuspid insufficiency
Defects amenable to percutaneous closure

Apical, outlet and mid-muscular - technically relatively easy to close with devices

Post-MI VSD - complex procedure - high failure rate: dependent on patient hemodynamic status

Post operative residual defects - achievable closure, dependent on anatomical details

Perimembranous - more complex with greater incidence of acute and longer term complications due to anatomical relationships
Established Indications for VSD closure

Left-to-right shunt >1.5:1

LV enlargement z-score >2

Increased PAP

Intractable CHF

Failure to thrive

Previous infective endocarditis (second episode)
Other Indications for VSD closure

Psychosocial impact on patient and family

Avoid stigmata of having a heart defect

Employability

Health insurance

Heavy vehicle license

Sports participation
Devices available for percutaneous closure
Risks associated with pmVSD Closure

• Surgical closure
  – cAVB occurrence reported at ~1%
  
  **Tucker** 2007 JACC: 4432 pts with pVSD, 1.1% PPM
  
  **Risk factors** - Down syndrome (41% vs. 18%)
  Younger age 14 vs. 24 months
  If weight >8 kg incidence only 0.8% PPM
  
  **Andersen** 2006 ATS: 996 isolated pVSD, 0.7%

  – Significant residual VSD 1-5%
  
  – Reoperation 2%
  
  – Mortality 0.5%
Age distribution of surgical pmVSD closure

Andersen 2006 ATS
Complications

Overall 12.7%
Significant 6.5%
- death 0.2%
- vascular 0.7%
- hemolysis 1.2%
- infection 0.5%
- embolization 0.9%
- TR 6.0% (mild/trival)
- AR 3.3% (OR in 2 pts)

Residual shunt (requiring OR) 0.7%

Arrhythmias
- tachyarrhythmias 0.7%
- early cAVB 2.8%

6/12 requiring PPM, <1 week after implant...presenting with syncope, asystole
Follow up

2 yr (range 6/12 to 10 yr)

- death 1 pt
- late cAVB 4 pt (4, 7, 12, 18 mons p/c)
  - syncopal 2
  - asymptomatic 2

95% complete closure in FU
Transcatheter closure of congenital ventricular septal defects: results of the European Registry

Table 3 Characteristics of patients with complete atrio-ventricular block

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (years)</th>
<th>Defect type</th>
<th>Post-surgical defect (yes/no)</th>
<th>Device type</th>
<th>Measure (mm)</th>
<th>Transient (Yes/No)</th>
<th>Therapy</th>
<th>Timing of occurrence post-procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4</td>
<td>pmVSD</td>
<td>No</td>
<td>A-ASD</td>
<td>4</td>
<td>No</td>
<td>Stop kt−surgery</td>
<td>1 day</td>
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<tr>
<td>2</td>
<td>2</td>
<td>pmVSD</td>
<td>No</td>
<td>A-pmVSD</td>
<td>12</td>
<td>No</td>
<td>PM</td>
<td>5 days</td>
</tr>
<tr>
<td>3</td>
<td>11</td>
<td>pmVSD</td>
<td>No</td>
<td>A-pmVSD</td>
<td>8</td>
<td>No</td>
<td>PM</td>
<td>5 days</td>
</tr>
<tr>
<td>4</td>
<td>55</td>
<td>mVSD</td>
<td>Yes</td>
<td>A-mVSD</td>
<td>10</td>
<td>Yes</td>
<td>PM</td>
<td>4 days</td>
</tr>
<tr>
<td>5</td>
<td>3.4</td>
<td>pmVSD</td>
<td>No</td>
<td>A-pmVSD</td>
<td>8</td>
<td>Yes</td>
<td>PM</td>
<td>3 days</td>
</tr>
<tr>
<td>6</td>
<td>4.2</td>
<td>pmVSD</td>
<td>No</td>
<td>A-pmVSD</td>
<td>8</td>
<td>No</td>
<td>PM</td>
<td>5 days</td>
</tr>
<tr>
<td>7</td>
<td>8.1</td>
<td>pmVSD</td>
<td>No</td>
<td>A-pmVSD</td>
<td>6</td>
<td>No</td>
<td>PM</td>
<td>5 days</td>
</tr>
<tr>
<td>8</td>
<td>11.6</td>
<td>mVSD</td>
<td>Yes</td>
<td>A-pmVSD</td>
<td>10</td>
<td>Yes</td>
<td>PM</td>
<td>4 days</td>
</tr>
<tr>
<td>9</td>
<td>5.2</td>
<td>mVSD</td>
<td>No</td>
<td>A-pmVSD</td>
<td>10</td>
<td>No</td>
<td>PM</td>
<td>3 days</td>
</tr>
<tr>
<td>10</td>
<td>1.5</td>
<td>mVSD</td>
<td>Yes</td>
<td>A-PDA</td>
<td>5/4</td>
<td>No</td>
<td>Stop kt−surgery</td>
<td>7 months</td>
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<tr>
<td>11</td>
<td>1.2</td>
<td>mVSD</td>
<td>No</td>
<td>A-PDA</td>
<td>8/6</td>
<td>Yes</td>
<td>PM</td>
<td>4 months</td>
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<tr>
<td>12</td>
<td>1</td>
<td>pmVSD</td>
<td>No</td>
<td>A-pmVSD</td>
<td>8</td>
<td>Yes</td>
<td>Stop kt−surgery</td>
<td>18 months</td>
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<tr>
<td>13</td>
<td>36</td>
<td>pmVSD</td>
<td>No</td>
<td>A-pmVSD</td>
<td>16</td>
<td>No</td>
<td>PM</td>
<td>12 months</td>
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<tr>
<td>14</td>
<td>1.2</td>
<td>pmVSD</td>
<td>No</td>
<td>A-pmVSD</td>
<td>8</td>
<td>No</td>
<td>PM</td>
<td>4 months</td>
</tr>
<tr>
<td>15</td>
<td>2.7</td>
<td>pmVSD</td>
<td>No</td>
<td>A-pmVSD</td>
<td>12</td>
<td>No</td>
<td>PM</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>2.6</td>
<td>pmVSD</td>
<td>No</td>
<td>A-pmVSD</td>
<td>8</td>
<td>No</td>
<td>PM</td>
<td></td>
</tr>
</tbody>
</table>

A-mVSD, Amplatzer muscular VSD occluder; A-pmVSD, Amplatzer perimembranous VSD occluder; A-ASD, Amplatzer atrial septal defect occluder; A-PDA, Amplatzer PDA occluder; PM, pace-maker implantation.

cAVB - 3.7% overall, PPM - 2.3% both early & late after implant
Multivariable analysis: factors associated with occurrence of complications: age & weight at the time of the procedure
The Chinese experience new implants for pmVSD

Modified double disk occluder - MDVO
Shanghai Shape Memory Alloy Ltd, China
The Chinese experience new implants for pmVSD

Inclusion criteria for closure
- age ≥3 years old
- maximum VSD diameter 16 mm by TTE
- defect located 9 to 11 o’clock in the short axis parasternal view
- left to right shunt
- PAP <70 mm Hg by TTE

Excluded were patients with
- AoV prolapse
- severe AR
- Right-to-left shunt
- Cyanosis
- PAP >70 mm Hg
- NYHA class IV

Qin et al AJC 2008
The Chinese experience with newer implants for pmVSD

- 5 centres in China, 412 patients, ages 3 - 65, mean 16 years
- VSD’s 3-18 mm
- Devices used were 4 - 20 mm, symmetric occluders in 312 pts, asymmetric occluders in 86 pts
- During and after device implant, 10 had LBBB and 16 RBBB...all recovered in <1 week
- 97% successful closure
- 6 patients (4 children and 2 adults) had cAVB (1.4%), recovered within 3 weeks with temp pacing and steroids
- Dislodgement rare: 3/412 (3/86; 0.03%) implants...asymmetric device
- No further complications in 0.5 to 2 years follow up

Qin et al AJC 2008
Table 1
Clinical characteristics of patients (n = 412)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>202 (49.0%)</td>
</tr>
<tr>
<td>Women</td>
<td>210 (51.0%)</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td></td>
</tr>
<tr>
<td>&lt;15</td>
<td>16.4 ± 9.1</td>
</tr>
<tr>
<td>≥15</td>
<td>228 (55.3%)</td>
</tr>
<tr>
<td>Pulmonary to systemic flow ratio</td>
<td>1.9 ± 0.4</td>
</tr>
<tr>
<td>Pulmonary pressure</td>
<td></td>
</tr>
<tr>
<td>&lt;40 mm Hg</td>
<td>296 (71.8%)</td>
</tr>
<tr>
<td>40 to 70 mm Hg</td>
<td>116 (28.2%)</td>
</tr>
<tr>
<td>Defect diameter by ventriculography (mm)</td>
<td>5.0 ± 2.7</td>
</tr>
<tr>
<td>Device diameter (mm)</td>
<td>7.1 ± 3.6</td>
</tr>
<tr>
<td>Rim below aortic valve (mm)</td>
<td>3.1 ± 1.2</td>
</tr>
<tr>
<td>Defect shape by ventriculography</td>
<td></td>
</tr>
<tr>
<td>Infundibular</td>
<td>230 (55.8%)</td>
</tr>
<tr>
<td>Aneurysmal</td>
<td>96 (23.3%)</td>
</tr>
<tr>
<td>Tubular</td>
<td>49 (11.9%)</td>
</tr>
<tr>
<td>Window-like</td>
<td>37 (9.0%)</td>
</tr>
</tbody>
</table>

Qin et al AJC 2008
Risk Factors and Outcomes of Post-Procedure Heart Blocks After Transcatheter Device Closure of Perimembranous Ventricular Septal Defect

- pmVSD closure in 228 patients
- Heart block occurred in 33 (14.5%) cases and average 3.0 days after the procedure
- The 3 cases with 3rd-degree AVB developed progressively from either a complete RBBB with a left anterior hemiblock or cLBBB with a 1st-degree AVB
- High-degree AVB in these 4 patients reverted to the NSR after administration of IV hydrocortisone and application of a temporary PM

| Table 1. Number of Cases That Developed Heart Blocks After Closure of pmVSD |
|-----------------------------|-----------------------------|
| Cases (n) | Average Time of Emergence of PPHBs (Days) |
| RBBB | 57.6% | 1–6 |
| CRBBB | 10 | 1–5 |
| IRBBB | 9 | 1–6 |
| LBBB | 24.2% | 1–5 |
| CLBBB | 3 | 1–3 |
| ILBBB | 5 | 2–5 |
| AVB | 18.2% | 3–7 |
| First-degree AVB | 1 | 3 |
| Second-degree AVB | 2 | 3 |
| Mobitz type 1 | 1 | 3 |
| Mobitz type 2 | 1 | 3 |
| Third-degree AVB | 3 | 4–7 |
| Total | 33 |  |
Risk Factors and Outcomes of Post-Procedure Heart Blocks After Transcatheter Device Closure of Perimembranous Ventricular Septal Defect

- Heart block reverted to normal in 21 prior to hospital discharge
- 12 cases (2-LBBB, 10-RBBB) did not recover by time of D/C...3 by 3 months follow up
- Follow up time was 58 months (83% completed follow up)

<table>
<thead>
<tr>
<th>Risk factors for HB</th>
<th>Patients With No PPHB (n = 195)</th>
<th>Patients With PPHB (n = 33)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>13.6 ± 10.2</td>
<td>15.1 ± 10.9</td>
<td>0.71</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>38.8 ± 18.9</td>
<td>40.2 ± 18.8</td>
<td>0.38</td>
</tr>
<tr>
<td>DLRD-SLT, mm</td>
<td>3.8 ± 1.6</td>
<td>2.3 ± 0.6</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>DAVD, mm</td>
<td>3.2 ± 1.5</td>
<td>3.9 ± 1.3</td>
<td>0.03</td>
</tr>
<tr>
<td>Diameter of pmVSD, mm</td>
<td>5.4 ± 2.1</td>
<td>5.3 ± 3.3</td>
<td>0.95</td>
</tr>
<tr>
<td>AVSDO/SVSDO*</td>
<td>91/104</td>
<td>15/18</td>
<td>0.90</td>
</tr>
<tr>
<td>SOD, mm</td>
<td>7.4 ± 2.6</td>
<td>8.8 ± 4.5</td>
<td>0.07</td>
</tr>
<tr>
<td>DDOV, mm</td>
<td>2.0 ± 0.7</td>
<td>3.5 ± 1.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>PASP, mm Hg</td>
<td>31.8 ± 6.0</td>
<td>32.2 ± 7.0</td>
<td>0.13</td>
</tr>
<tr>
<td>LVDD before procedure, mm</td>
<td>43.5 ± 7.8</td>
<td>45.1 ± 6.9</td>
<td>0.69</td>
</tr>
<tr>
<td>LVDD after procedure, mm</td>
<td>41.3 ± 6.8</td>
<td>42.9 ± 6.9</td>
<td>0.66</td>
</tr>
<tr>
<td>Procedure time, min</td>
<td>86.5 ± 25.1</td>
<td>89.5 ± 29.8</td>
<td>0.52</td>
</tr>
<tr>
<td>Fluoroscopy time, min</td>
<td>18.2 ± 8.4</td>
<td>19.2 ± 11.2</td>
<td>0.22</td>
</tr>
</tbody>
</table>

Anatomical and device characteristics

- **DAVD** the aortic valve to the defect
- **DDOV** diameter difference between the occluder and VSD
- **DLRD-SLT** the distance from lower rim of the defects to the septal leaflet of the TV
- **SOD** size of device
Why the difference in incidence of cAVB?

**Age:**
Most patients were adults or older children

**Anatomy:**
In children, device/ventricular septum area is larger

**Device design:**
Waist is longer in the MDVO than the Amplatzer occluder (2 to 2.5 mm vs. 1.5 mm)

**Risk of cAVB:**

**Age:**
children <10 years

**Anatomy:**
true pmVSD, location of penetrating bundle to defect margins

**Technical:**
crossing the defect with difficulty or development of right bundle block (and left anterior hemiblock) during the procedure
Promotes Closure and Stability

- Polyester-filled waist and discs promotes closure of the defect
- Inner braid layer and LV disc shape promotes stability
AMPLATZER® Membranous VSD Occluder 2

Radial Force

Clamp Force

Device Stability

75% Reduction

45% Reduction
Problems in assessing complications and outcomes

Inconsistent definition of anatomy: are you closing a...
  pmVSD
  muscular defect: in trabecular septum
  muscular outlet
    infundibular
    intracristal
  a VSD with aneurysm

Age and weight of patients treated

Indications for intervention
Despite these inconsistencies in assessing outcomes, transcatheter techniques have improved due to a better understanding of:

- anatomy
- improved device design
- recognition of potential at risk populations
Cám ơn
Thank you
# Incidence of Complete AV Block (cAVB)

<table>
<thead>
<tr>
<th>Source</th>
<th>Incidence</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Xunmim et al, Int J Cardiol 2007 (China)</td>
<td>1/72 (1.4%)</td>
<td>Transient</td>
</tr>
<tr>
<td>Butera G et al, JACC 2007 (Milan)</td>
<td>3/87 (3.4%)</td>
<td>SX or PPM</td>
</tr>
<tr>
<td>Pedra CAC et al, J Invasive Cardiol 2008 (Brasil)</td>
<td>1/39 (2.6%)</td>
<td>PPM</td>
</tr>
<tr>
<td>Zhou J et al, Clin Cardiol 2008 (China)</td>
<td>4/168 (2.4%)</td>
<td>Transient</td>
</tr>
<tr>
<td>Oses P et al, Ann Thorac Surg 2010 (Montreal)</td>
<td>2/35 (5.7%)</td>
<td>PPM</td>
</tr>
<tr>
<td>Zuo J et al, Am J Cardiol 2010 (China)</td>
<td>6/294 (2.0%)</td>
<td>SX or PPM</td>
</tr>
<tr>
<td>Yang R et al, Cath Cardiovasc Intervent 2011 (China)</td>
<td>1/60 (1.6%) [13 transient]</td>
<td>PPM</td>
</tr>
<tr>
<td>US Phase I Trial</td>
<td>2/35 (5.7%)</td>
<td>PPM</td>
</tr>
<tr>
<td>Survey – JLB 2007</td>
<td>12/486 (2.5%) [6 transient]</td>
<td>PPM</td>
</tr>
<tr>
<td>Tucker E et al, JACC 2007 Surgical &gt;8kg Multicenter, PCCC</td>
<td>13/1739 (0.8%) [3 late]</td>
<td>PPM</td>
</tr>
</tbody>
</table>
AMPLATZER® Membranous VSD Occluder I

- Had an eccentric shape, with the distal (LV) disk exceeding the connecting waist by 1 mm in its superior part and by 5.5 mm in its inferior part.
- Proximal (RV) disk 2-mm l>the connecting waist, which was only 1.5 mm in length.
- Available sizes range from 4 to 18 mm.
Complete heart block