CATHETER CLOSURE OF CONGENITAL/ACQUIRED MUSCULAR AND PERIMEMBRANOUS VSDs USING THE AMPLATZER DEVICES

BASIL (VASILIOS) D. THANOPoulos MD, PhD
“AGHIA SOPHIA” CHILDREN’S HOSPITAL
ATHENS - GREECE
CATHETER CLOSURE OF CONGENITAL/ACQUIRED MUSCULAR AND PERIMEMBRANOUS VSDs USING THE AMPLATZER DEVICES

BACKGROUND

During the last decade a variety of devices (RDU, Clamshell / Buttoned device) have been used for transcatheter closure of VSDs, but none has gained wide acceptance.

DRAWBACKS

- Large delivery sheaths
- Inability for repositioning-redeployment
- Embolization of the device
- Aortic/atrioventricular valve damage
- High rate of residual shunting
CATHETER CLOSURE OF CONGENITAL/ACQUIRED MUSCULAR AND PERIMEMBRANOUS VSDs USING THE AMPLATZER DEVICES

1999
AMPLATZER VSD OCCLUDER
Repositionable
6F TO 10 delivery sheath
Self-centering
Round disks
Stenting effect
Asymmetric left disk (AAVSDO)

2001
AMPLATZER ASYMMETRIC VSD OCCLUDER
CONGENITAL MUSCULAR VENTRICULAR SEPTAL DEFECT CLOSURE WITH THE AMPLATZER VSD OCCLUDER

“AGHIA SOPHIA” CHILDREN’S HOSPITAL, ATHENS (21pts)
ROYAL BROMPTON HOSPITAL, LONDON (10pts)

Thanopoulos- Rigby: Heart 2005
PATIENT POPULATION

33 patients,
Age: 4M-43Y  Weight: 4.2-78kg

DIAGNOSIS

  Single MVSD: 30 pts
  CTGA: 2 pts
  TGA-Mustard: 1pt
PATIENT SELECTION CRITERIA

1. Defect Size $\leq$ 18 mm (ECHO – Angio measurement).
2. Patient’s BW $\geq$ 5 kg.
3. Distance $> 4$ mm from the margins of the defect to the Aortic, Mitral and Tricuspid valves.
4. Significant L$\rightarrow$R shunt.
5. Recurrent Endocarditis (small defects $\geq$ 3 mm).
6. Single or multible defects
7. Swiss Cheese type defects with main central opening
Side view of the Amplatzer Muscular Ventricular Septal Defect Occluder (AMVSDO) made of tightly woven 0.004” Nitinol wires into two flat disks with a 7 mm connecting waist. The left ventricular disk (4 mm larger than the waist) is on the right and the right ventricular disk (3 mm larger than the waist) is on the left of the panel.
PROCEDURE

CARDIAC CATHETERIZATION (DIAGNOSTIC STUDY):

1. Hemodynamics

BIPLANE (MULTIPLANE) TEE + COLOR DOPPLER

1. Defect Size, Anatomic Correlation.
2. Guidance of the procedure.
3. Evaluation of the residual Shunts.
Implantation Technique (Venous Route)

Mid and Apical MVSDs

(18 pts and 6 pts, respectively)

- **Crossing the Defect:**
  - 4F (5F) Cobra Catheter from LV.

- **Formation of an Arteriovenous Loop (Femoral Artery – Jugular Vein):**
  - Soft J-tipped 260 cm wire (standard, Amplatz, Terrumo) snared from the PA (Amplatz gooseneck snare – Microvena).

- **Balloon Sizing of the Defect:**
  - 7F balloon-tipped, end-hole catheter or pulmonary balloon occlusion catheter (Medi-Tech).

- **Selection of the Device:**
  - Waist diameter equal to balloon “stretched” diameter.

- **Introduction of the Delivery System:**
  - 6F to 9F delivery system (introduction is facilitated by tightening of the wire loop.

- **Delivery of the Device:**
  - TEE and fluoroscopic guidance.
Figure 2:

Steps of transcatheter closure of a mid-muscular ventricular septal defect with the AMVSDO (long axial oblique projection).

1: Crossing the defect with a 4F Cobra catheter.

2: Arteriovenous loop and balloon sizing.
IMPLANTATION TECHNIQUE (VENOUS ROUTE)
MID AND APICAL MVSDs
(18 and 6 pts, respectively)
IMPLANTATION TECHNIQUE (VENOUS ROUTE)
MID AND APICAL MVSDs
(18 pts and 6 pts, respectively)
Four chamber view transesophageal echocardiographic guidance of transcatheter muscular ventricular septal defect closure, with modified Amplatz device.

1: Deployment of the left ventricular disc.

2: The left ventricular disc has been pulled against the ventricular septum.

3: Deployment of the right ventricular disc.

4: Color Doppler obtained immediately after implantation of the prosthesis. Note good position of the device with no evidence of residual shunt.
IMPLANTATION TECHNIQUE (VENOUS ROUTE)
ANTERIOR AND OUTLET (SUB-PULMONARY) MVSDs (9 pts)

Crossing the Defect:
- Balloon-tipped, end-hole Catheter (or Multipurpose or Cobra)
  From RV.

Guide Wire:
- Introduction of an Amplatz 0.035” super stiff ST-1 exchange wire (Medi-Tech).

Balloon Sizing of the Defect:
- 7F balloon-tipped, end-hole catheter or pulmonary balloon occlusion catheter (Medi-Tech).

Selection of the Device:
- Waist diameter equal to balloon “stretched” diameter.

Introduction of the Delivery System:
- Over the exchange wire or the long sheath over the balloon catheter.

Delivery of the Device:
- TEE and fluoroscopic guidance.
IMPLANTATION TECHNIQUE (VENOUS ROUTE) ANTERIOR AND OUTLET (SUB-PULMONARY) MVSDs (9 pts)
RESULTS

Qp / Qs: 1.7-3.4

Stretched VSDd: 6-14mm

Device size: 6-14mm

Complete closure

IMM: 31 / 33 (94%)  
FU: 32 / 33 (97%)
COMPLICATIONS

**EARLY**

- TCLBBB: 4 pts
- MISPLACED DISK: 2 pts
- DEVICE EMBOL: 1pt

**LATE**

- Complete heart block 1pt
Follow-up cath

Long axial oblique left (A) and right and left (B) ventriculograms 2 years after implantation of an Amplatzer ventricular septal occluder. Note complete closure, excellent position of the device and no evidence of device failure.
PERCUTANEOUS CLOSURE OF CONGENITAL/ACQUIRED MVSDs
PERCUTANEOUS CLOSURE OF CONGENITAL/ACQUIRED MVSDs

Results of published studies AMVSDs using the AMVSDO
## Percutaneous Closure of Congenital/Acquired MVSDs

### Results of published studies AMVSDs* using the AMVSDO

<table>
<thead>
<tr>
<th>Series</th>
<th>Age (y)</th>
<th>VSD-d (mm)</th>
<th>Dd (mm)</th>
<th>RS</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holtzer et al</td>
<td>n = 18</td>
<td>52-86</td>
<td>6-22</td>
<td>12-24</td>
<td>T=60%</td>
</tr>
<tr>
<td>CCI 2004</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M=20%</td>
</tr>
</tbody>
</table>

* = Post infraction VSDs

Death: 41% (S=19-46%)

Procedural rare
10 YEARS EXPERIENCE WITH TRANSCATHETER CLOSURE OF PERIMEMBRANOUS VENTRICULAR SEPTAL DEFECTS USING THE AMPLATZER ASYMMETRIC PERIMEMBRANOUS VENTRICULAR SEPTAL DEFECT OCCLUDER: A MULTICENTER STUDY

Basil D. Thanopoulos, Michael L. Rigby, Evangelos Karanasios, George Tsaussis, Niko Blom, Dan Deleanou,
Departments of Cardiology Iatrikon Medical Center, Athens, Greece, Royal Brompton Hospital, London, UK, “Aghia Sophia” Children’s Hospital, Athens, Greece University Hospital, Leiden, NL, Ares Clinic, Romania
PATIENT POPULATION I

78 patients
Age: 0.3–14y (m: 5.1)
Weight: 5–49kg (m: 22)

DIAGNOSIS
Single MVSD: 30 pts
CTGA: 3 pts
TGA-Mustard: 1 pt
Kirklin type II: 68 pts
Gerbode-like: 5 pts
Post-op Residual VSD: 5 pts

Single PMVSD: 74 pts
TGA: 2 pts
SubAS: 2 pts
PATIENT SELECTION CRITERIA

1. Maximal defect size < 18 mm (ECHO - Angio measurement).
2. Patient’s BW $\geq$ 5 kg.
3. Distance $\geq$ 1 mm from the margins of the defect to the Aortic valve.
4. Significant L$\rightarrow$R shunt.
5. Recurrent Endocarditis
PROCEDURE - IMPLANTATION

- **Crossing the Defect:**
  - 4F (5F) Cobra Catheter from LV.

- **Formation of an Arteriovenous Loop (Femoral artery - Femoral vein):**
  - Soft J-tipped 260 cm wire (Amplatz Ropewire) snared from the PA or SVC.

- **Selection of the Device:** Waist diameter 1–2 mm > maximal defect diameter.

- **Delivery of the Device:** 7F to 9F delivery system.
  - Guidance: TEE and fluoroscopic guidance.
RESULTS

Qp / Qs: 1.9-2.7
PMVSDd: 5-15mm
Device size: 6-16mm
DI: 72 / 78

Complete closure

IMM: 67 / 72 (93%)
FU: 70 / 72 (97%)
RESULTS

Perimembranous VSD: Kirklin type I

VSD + S. Aneurysm
RESULTS

RESIDUAL POST TGA
REPAIR PMVSD (BW: 5 KG)
FOLLOW-UP (2-10 YEARS)

1, 3, months, Serially/6 months

1-2 years : CC+Angio

Chest X-ray
ECG
24-hour Holter ECG
TEE - color Doppler
Time course of residual shunt disappearance

% 30
25
20
15
10
5
0
24h 1m 3m 6m 1y

Thanopoulos et al

*= Tr (1pt)+Sm (1pt) - RS

*= 3.%
FOLLOW-UP : 2-10 years

Ascending aortogram, left ventriculogram and TEE 2 years after PMVSD closure
COMPLICATIONS

EARLY

- TCLBBB: 3 pts
- NSVT: 1 pts
- SVT: 2 pts
- Mobitz II AVB 3 pts *
- CHB 1 pt *
- Tr severe bradycardia: 5 pts
- Device embolization: 3 pts

LATE

- Complete heart block: 1pt

* = SR after device removal
COMPLICATIONS

DEVICE EMBOLIZATION
ADO II: 2008
Although moderately difficult to perform, transcatheter implantation of the Amplatzer VSD occluders appears to be an effective and safe treatment in selected patients with muscular and perimembranous VSDs, respectively. The ADO II can be used as an alternative device in defects up to 6.5 mm in diameter.
PERCUTANEOUS CLOSURE OF CONGENITAL/ACQUIRED MUSCULAR AND PERIMEMBRANOUS VSDs

Results of published studies MVSDs using the AMVSDO

<table>
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<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holtzer et al 2004</td>
<td>75</td>
<td>0.1-54</td>
<td>3-16</td>
<td>4-16</td>
<td>92.3%</td>
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<td></td>
<td></td>
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<td>Death(2.7%)</td>
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<td></td>
<td>34(43%)</td>
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<td></td>
<td>DI(87%)</td>
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<tr>
<td></td>
<td>17(25.8%)</td>
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<td></td>
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<td>Embol(2.7%)</td>
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<td>Perfor(1.4%)</td>
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<td>Arrhythmias</td>
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<td></td>
<td>(20%)</td>
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<td></td>
<td></td>
<td>Hypotension/</td>
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<td></td>
<td></td>
<td></td>
<td>Cardiac arrest (12%)</td>
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<td></td>
<td></td>
<td></td>
<td>Weight&lt;5Kg</td>
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<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>(53.8%)</td>
</tr>
</tbody>
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PATIENT SELECTION CRITERIA

1. Maximal defect size < 18 mm (ECHO - Angio measurement).
2. Patient’s BW > 8 kg.
3. Distance ≥ 1 mm from the margins of the defect to the Aortic valve.
4. Significant L→R shunt.
5. Recurrent Endocarditis
AMPLATZER ASYMMETRIC VSD OCCLUDER

Side view of the AAVSDO. The arrow indicates the superior rim of the asymmetric left disk.
10 days later, Second procedure:
5 more Devices implanted
Qp/Qs: 1:1; PASP: 3/4 systemic
6-months later, normal PAP
10 days later, Second procedure:
5 more Devices implanted
Qp/Qs: 1:1; PASP: 3/4 systemic
6-months later, normal PAP
LOADING SYSTEM
PROCEDURE

**CARDIAC CATHETERIZATION (DIAGNOSTIC STUDY):**

1. Hemodynamics

**BIPLANE (MULTIPLANE) TEE + COLOR DOPPLER**

1. Defect Size, Anatomic Correlations.
2. Guidance of the procedure.
3. Evaluation of the residual Shunts.
PERIMEMBRANOUS VENTRICULAR SEPTAL DEFECT CLOSURE WITH THE AMPLATZER ASYMMETRIC VSD OCCLUDER

“AGHIA SOPHIA” CHILDREN’S HOSPITAL, ATHENS - IPPOKRATATION HOSPITAL, ATHENS UNIVERSITY (26pts)
ROYAL BROMPTON HOSPITAL, LONDON (6pts)
LEIDEN UNIVERSITY MEDICAL CENTER (3pts)
IMPLANTATION TECHNIQUE

- **Crossing the Defect:**
  4F (5F) Cobra Catheter from LV.

- **Formation of an Arteriovenous Loop (Femoral artery - Femoral vein):**
  Soft J-tipped 260 cm wire (Amplatz Ropewire) snared from the PA or SVC (Amplatz gooseneck snare - Microvena).

- **Selection of the Device:**
  Waist diameter 1-2 mm > maximal defect diameter.

- **Introduction of the Delivery System:**
  7F to 10 delivery system (introduction is facilitated by tightening of the wire loop).

- **Delivery of the Device:**
  TEE and fluoroscopic guidance.
PROCEDURE - LOADING
PROCEDURE - IMPLANTATION

A. Long axial oblique left ventriculogram showing a perimembranous VSD.

B. Advancement of a 7F Amplatzer delivery system over a deflected towards to the left ventricular apex guidewire.

C. Hand injection of contrast medium into the left ventricle showing an appropriately positioned left ventricular disk.

D. Deployment of the right ventricular disk.

E. Left ventriculogram after release of the AAVSDO demonstrating complete closure with good device position.

F. Ascending aortogram after the release of the device revealing absence of aortic regurgitation.
RESULTS

Qp / Qs: 1.5 - 2.7

MVSDd: 2 - 10mm

Device: 4 - 16mm

Device implantation: 34/35

Complete closure

IMM : 30/34 (88.2%)  FU : 32/34(35) (94%-91.4%)
Catheter Closure of Perimembranous/membranous VSDs.

Perimembranous VSD: Kirklin type I
Catheter Closure of Perimembranous/membranous VSDs.

PMVSD + S. Aneurysm
Catheter Closure of Perimembranous/membranous VSDs.

Gerbode-like VSD
Catheter Closure of Perimembranous/membranous VSDs.

COMPLICATIONS
PERCUTANEOUS CLOSURE OF CONGENITAL/ACQUIRED MUSCULAR AND PERIMEMBRANOUS VSDs

Figure 5
PERCUTANEOUS CLOSURE OF CONGENITAL/ACQUIRED MUSCULAR AND PERIMEMBRANOUS VSDs

Figure 6
Results of published studies PMVSDs using the APMVSDO

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<tbody>
<tr>
<td>Holtzer et al 2003 *</td>
<td>61 (59)</td>
<td>0.7-58</td>
<td>3-13</td>
<td>4-16</td>
<td>65% AR/TR</td>
</tr>
<tr>
<td>PICS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(19/29) (7.4/16.2%)</td>
</tr>
<tr>
<td>Bass et al 2003</td>
<td>27</td>
<td>1.25-32</td>
<td>1.6-8mm</td>
<td>4-12</td>
<td>92% Tr.AR?)</td>
</tr>
<tr>
<td>CCI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(1/25)</td>
</tr>
</tbody>
</table>
PERCUTANEOUS CLOSURE OF CONGENITAL/ACQUIRED MUSCULAR AND PERIMEMBRANOUS VSDs

What proportion of PeMVsDs are suitable for closure?

- Children: 75%
- Infants: 25%

Perimembranous VSDs: 75%

Muscular VSDs: 10%

Subarticular VSDs: 10%

Inlet VSDs: 5%
RESULTS
RESULTS
Steps of transcatheter closure of an anterior muscular septal defect with the AVSDO

A. Left ventriculogram showing an anterior MVSD

B. Crossing the defect with a balloon end-hole catheter from the right ventricle

C. Advancement of an exchange wire and balloon sizing (arrow)

D. Deployment of the left ventricular disk

E. Deployment of the right ventricular disk

F. Left ventriculogram after release of device showing complete closure
Steps of transcatheter muscular VSD closure using the AVSDO in a patient 2-month-old with corrected transposition of the great arteries

A. Left ventriculogram in a modified 4-chamber view showing a large outlet MVSD.

B. Hand injection of contrast medium into the left ventricle showing an appropriately positioned left disk.

C. Deployment of the right disk.

D. Long axial oblique left ventriculogram after release of the device revealing complete closure with good positioned device.
Steps of transcatheter muscular VSD closure using the AVSDO

A. Long axial oblique left ventriculogram showing a large mid-muscular VSD.

B. Hand injection of contrast medium into the left ventricle showing an appropriately positioned left disk.

C. Deployment of the right disk.

D. Long axial oblique left ventriculogram after release of the AVSDO showing complete closure with good device position.
COMPLICATIONS

Device embolization

A. Left ventriculogram after release of device showing complete closure with good position of AAVSDO

Device embolization into the aorta due to inadvertent dislodgment during removal of pigtail catheter.

B-C. Successful removal using a basket type retrieval catheter.

D. Successful closure of the defect using an other AAVDO
PROCEDURE - LOADING

A. Delivery system of the AAVSDO. Arrows indicate the negative and positive adaptors of the microscrew mechanism (upper arrow) and the metal slot (lower arrow) of the delivery catheter., respectively.

B. Side view showing an optimally loaded AAVSDO with its superior left rim in line with the superior curve of the delivery catheter.

C. Tightening of the plastic vice on the delivery cable.

D. Loader used for introduction of the AAVSDO into the delivery sheath.
NO DICLOSURE
RELASHIONSHIP
TO DICLOSE