Ventricular Septal Defects: Closure, Devices & Techniques

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Disclosures

• None to declare
Objectives

- Introduction
- Indications/ contraindications
- Device timeline/ history
- Approach/ technique
- Outcomes
Introduction

- Diagnosis represents approximately 20%-30% of patients with congenital heart disease.

- Large ventricular septal defects may be diagnosed prenatally or during infancy and may bring about congestive heart failure requiring surgical referral.

- Smaller defects may be moderate in dimension but over time may become smaller through the development of aneurysmal tissue.
Introduction

Yet despite being smaller, they too can be associated with long-term issues, such as:

- Left ventricular dilation
- Aortic valve insufficiency
- Double chamber right ventricle
- Arrhythmia
- Pulmonary hypertension
- Endocarditis
Anatomy of VSD’s

- Divided into:
  - Atrioventricular canal type (inlet)
  - Muscular
  - Membranous
  - Conoventricular (hypoplasia or malalignment type)
  - Conal septal or RV outlet

- *Transcatheter* closure typically reserved for *membranous* and *muscular*
Indications for closure

- Typically outside of the neonatal period and not associated with other surgical indications
  - History of infective endocarditis
  - Failure to thrive
  - Worsening New York Heart association classification
  - Recurrent respiratory illnesses
  - Estimated Qp/Qs of >1.5
Contra-indication for transcatheter occlusion

- Irreversible pulmonary hypertension (PVRi > 7 Woods units)
- Contra-indication to antiplatelet therapy
- Active infectious issues
- Anatomic concerns:
  - <2 mm rim below the aortic valve
  - Aortic valve prolapse
  - Malalignment type defects
  - Supra-cristal defects
In the beginning....

1984

Early experiments in transportation
Initial attempts

• A: double umbrella device
  • Polyurethane foam on hexagonal stainless steel frame (17mm device)

• B: Sideris buttoned device
  • Square sheet of polyurethane foam with diagonally oriented, independent wire arms and separate counter occluder (1997)

Initial attempts

- C & D: Bard clamshell device
  - Two opposing self-expanding umbrellas
  - Withdrawn from investigation due to arm fractures and unacceptably high incidence of residual shunts

**Table 1. Reports on transcatheter closure of ventricular septal defects in literature**

<table>
<thead>
<tr>
<th>Investigators</th>
<th>Time</th>
<th>Patient Number</th>
<th>Diagnosis</th>
<th>Devices</th>
<th>Closure Results and Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lock JE, et al</td>
<td>1988</td>
<td>6</td>
<td>3 postinfraction, 2 peri VSDs, 1 musc VSD</td>
<td>Rashkind double umbrella</td>
<td>5/6 residual shunts, 4 pts died, 1 complete closure</td>
</tr>
<tr>
<td>OLaughlin MP, et al</td>
<td>1989</td>
<td>1</td>
<td>Residual VSD after Fontan</td>
<td>Rashkind double umbrella</td>
<td>Residual shunt became smaller</td>
</tr>
<tr>
<td>Bridges ND, et al</td>
<td>1990</td>
<td>12</td>
<td>Congenital VSDs</td>
<td>Rashkind double umbrella</td>
<td>Residual shunt became smaller</td>
</tr>
<tr>
<td>Preminger TJ, et al</td>
<td>1994</td>
<td>7</td>
<td>Musc VSDs</td>
<td>Rashkind double umbrella</td>
<td>Residual shunt became smaller</td>
</tr>
<tr>
<td>van der Velde ME, et al</td>
<td>1994</td>
<td>29</td>
<td>Musc VSDs</td>
<td>Bard Clampsh</td>
<td>17% complete closure</td>
</tr>
<tr>
<td>Vogel M, et al</td>
<td>1996</td>
<td>1</td>
<td>Peni VSD</td>
<td>Rashkind double umbrella</td>
<td>Trivial residual shunt</td>
</tr>
<tr>
<td>Sideris EB, et al</td>
<td>1997</td>
<td>2</td>
<td>Musc VSDs</td>
<td>Amplatzier septal occluder</td>
<td>Trivial residual shunt</td>
</tr>
<tr>
<td>Lee EM, et al</td>
<td>1998</td>
<td>1</td>
<td>Postinfraction VSD</td>
<td>Amplatzier VSD occluder</td>
<td>Trivial residual shunt</td>
</tr>
<tr>
<td>Tofeig M, et al</td>
<td>1998</td>
<td>1</td>
<td>Musc VSD</td>
<td>Amplatzier VSD occluder</td>
<td>Trivial residual shunt</td>
</tr>
<tr>
<td>Thanopoulos BD, et al</td>
<td>1999</td>
<td>6</td>
<td>Musc VSDs</td>
<td>Amplatzier VSD occluder</td>
<td>Complete closure, 2 transient complete LBBB</td>
</tr>
<tr>
<td>Janorkar S, et al</td>
<td>1999</td>
<td>16</td>
<td>Musc VSDs</td>
<td>Rashkind double umbrella</td>
<td>2/16 died, 9/16, 5/16 and 5/16 had residual shunts immediately, 6 and 12 months after procedure</td>
</tr>
<tr>
<td>Latiff HA, et al</td>
<td>1999</td>
<td>1</td>
<td>Musc VSD</td>
<td>Gianturo coils</td>
<td>Small residual shunt</td>
</tr>
<tr>
<td>Kalra GS, et al</td>
<td>1999</td>
<td>30</td>
<td>28 peri VSDs, 2 musc VSDs</td>
<td>Rashkind double umbrella</td>
<td>87% successfully deployed, 30% residual shunts, 1 device embolization</td>
</tr>
<tr>
<td>Rodes J, et al</td>
<td>2000</td>
<td>1</td>
<td>Musc VSD</td>
<td>Amplatzier duct occluder</td>
<td>Complete closure at 4 months</td>
</tr>
</tbody>
</table>
Refinement of technology

- **Amplatzer devices**
  - Comprised of “Nitinol”, 55% nickel and 45% titanium alloy with super-elasticity and biocompatibility †
  - The Amplatzer muscular septal occluder is a double disc device
  - Nitinol thickness is 0.004” for devices <10mm & 0.005 for >10mm
  - The leading retention disc is 4mm greater than the waist and the proximal disc is 3mm larger than the waist
  - There is a securely sewn polyester thread into the two discs and waist of the device

Amplatzer results

- Initially reported by Lee et al** in 1998
  - Deployment into a 50 year old male with a post-infarct VSD with complete occlusion & significant clinical improvement
  - **Device was not FDA approved**
- Results of animal studies with surgically created VSD’s demonstrated complete success and a 100% closure rate via perventricular approach ‡
- First human implantation, an 8 month old toddler after attempted surgical VSD closure

Amplatzer results continued

- The first *transcatheter* approach was reported by Tofeig in 1999 ¥
  - 5 year old female with a mid-muscular defect.
  - 3 months post implantation a 1mm residual shunt was noted with excellent clinical improvement.
- Largest cohort reported was published in 2000 by Hijazi et al* with excellent closure rates and 100% complete occlusion at 6 month follow-up:
  - Noted complication/observation was transient arrhythmia noted during and immediately post procedure.

Advantages of the Amplatzer device

• Simple user-friendly delivery system
• Requires small sheaths
• Transcatheter device deployment & release from prograde or retrograde approach as well as perventricular
• Multiple device sizes
• Ability to reposition/ recapture device prior to release
Prior to intervention

- **Delineation of patient candidacy is crucial**
  - A complete hemodynamic assessment
    - +/- pulmonary hypertension study to delineate pulmonary vasoreactivity

- **Imaging**
  - Transesophageal or intracardiac echocardiography is important prior to, during and post device release (either in the cath lab or in the OR)

- **Approach often dictated by:**
  - Patient size
  - Defect location
  - Defect size
  - Vascular access history
Approach: *antegrade deployment & release*

- Establishment of an atrioventricular loop (A-V loop):
  - Used for membranous, muscular, post-surgical and post infarct defects

- A retrograde passage of a guidewire using either an angled glide catheter or Judkins right coronary catheter allowing for the an 0.035” exchange length guidewire snared from the pulmonary artery or the superior vena cava to be externalized to form the “A-V loop”

- The delivery catheter is then advanced over the wire from the venous access point into the descending aorta

- Transesophageal echocardiography can facilitate deployment of the device and interrogate the relationship of the surrounding structures with the device and document residual shunts
Approach: retrograde deployment & release

- An angled glide catheter or Judkins right coronary catheter is used to cross the defect
- An 0.035” guidewire is used to externalize the catheter and allow for the introduction of the delivery sheath or coronary guide-catheter
- With adjunctive imaging, transesophageal echocardiography, the distal retention disc is deployed in the right ventricle
- The delivery sheath and device are retracted to the septum and the sheath is retracted to deploy the proximal disc
Approach: *hybrid/ perventricular*

- A sternotomy or limited sternotomy is performed to allow for exposure of the right ventricular free wall and placement of a purse-string suture placement for sheath introduction.
- Transesophageal echocardiography or epicardial echocardiography can help guide wire crossing allowing for accurate positioning & advancement of a sheath into the left ventricle.
- Deployment is visualized with echocardiography and defect & device relationship is reviewed.
Outcomes

Catheter closure using the new clinical experience

Initial human experience with the Amplatzer perimembranous ventricular septal occluder device

Ziyad M. Hijazi MD, Aktham Hiari MD, Qi-Ling Cao and Ziyad M. Hijazi

First published: 12 July

Journal of the American College of Cardiology

Volume 47, Issue 2, January 2006

Transcatheter Closure of Perimembranous Ventricular Septal Defects Using the New Amplatzer Membranous VSD Occluder
Results of the U.S. Phase I Trial

Yun-Ching Fu, John Bass, Zahid Amin, Wolfgang Radtke, John P. Cheatham, William E. Hellenbrand, David Balzer, Qi-Ling Cao and Ziyad M. Hijazi

Outcomes

• Amplatzer membranous VSD occluder
  • Phase I clinical trial revealed a 91% closure rate with 96% complete closure rate at 6 month follow-up
  • One case of congenital heart block (CHB)

Further investigations with membranous device
Outcomes

- The longer term follow-up of patients began to identify an increasing incidence of post-procedural heart block.

- Rates of heart block between 2%-22%

- Predescu’s investigation postulated the decreasing patient size was an important factor although it was difficult to identify this as the sole risk factor.

- Given the identified concerns for unpredictable and late onset of heart block, the pmVSD device was not approved for use by the FDA.
Modifications for pmVSD device

- A structural modification reducing the radial force and increasing device stability performed well in a small study of 19 patients.
- Successful closure in 95% of patients with appreciable no aortic insufficiency, tricuspid valve insufficiency and no instances of heart block at 1 year follow-up.
Amplatzer muscular occluder

- 2004 brought about the results of a multi-institutional registry
2004: Multicenter Registry

- **Cohort:** 75 patients (83 procedures percutanesous & perventricular)
- **Median age:** 1.4 years (range 0.1-54 years)
- **Defect size:** median 7mm (3mm-16mm)
- **Outcome data:**
  - Procedural success: 87%
  - Residual shunt (@ 12 mos): 8%
  - Procedure related complication: 10%
2004: Multicenter Registry

- **Major adverse events:**
  - 2 procedure related deaths (2.7%)
  - Conduction anomalies 20% with no incidence of heart block requiring pacemaker
  - Device embolization – 2 patient
  - Cardiac perforation – 1 patient

- **Results:**
  - 24 hour post-procedural occlusion rate: 47.2%
  - 6 month post-procedural occlusion rate: 69.6%
  - 12 month post-procedural occlusion rate: 92.3%

- **Device received FDA approval in 2007**
Off-label occlusive devices...

19 of 21 patients with procedural success rate (90%)
- Median: F/U 1.9 yrs
- 83% with no or trivial shunt
- 94.7% without clinical complaints or signs of heart failure
Fig. 1. Pictorial representation of the anatomy of PMVSD with aneurismal tissue. (a) Illustrates where the measurements were taken. A: measurement at the left ventricular opening of the VSD. B: largest diameter of the aneurysm, usually in the mid-segment of the aneurysmal socket. C: measurement at the right ventricular opening of the VSD aneurysm, usually the smallest diameter of the defect. (b) Illustrates the angle between the opening of the VSD and the interventricular septum.

(b) Angiogram in the same projection demonstrating the ADO I in the aneurysm with the whole retention disc well within the aneurysm.
Off-label occlusive devices…

Off-label occlusive devices...

- **Amplatzer Ductal Occluder II (ADOII)**
  - Procedural success rates of 90%¥ - 93.5%#
  - Complete occlusion rates of 93.6% to 95% at f/u
  - Rare heart block incidence ‡

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Off-label occlusive devices…

Fig. 1 Levogramm (4-year-old boy) in 60° RAO projection with VSD: a left to right shunt; b after closure of the VSD with ADO II (5/6 mm), no residual shunt was seen. RCA right coronary artery, AV aortic valve, Cath angiography catheter, LV left ventricle

ADOII deployment in retrograde fashion
TEE imaging
TEE imaging
TEE imaging
Adverse events

- Conduction abnormalities
  - Risk factors have been difficult to identify
  - Postulated mechanism is the radial force of the device onto the conduction system
  - Carminati et al., have proposed that smaller patients and device oversizing could lend to increased incidence of heart block
  - Yang et al., suggested that an increased distance from the aortic valve, approximating the septal rim and tricuspid valve tended towards heart block

† Yang et al. Risk factors and outcomes of post-procedure heart blocks after transcatheter device closure of perimembranous VSD. JACC Cardiovasc Interv 2012;5(4):422-7

Adverse events

- **Hemolysis**
  - 1-2% of cases
  - Self-resolving in 48-72 hours
  - Rarely need transfusions or referral for surgical explantation

- **Aortic valve distortion**
  - 9% of patients
  - Minimum distance estimated at 2mm
  - Careful considerations taken when using ADOII or Amplatzer mVSD occluder
  - Deployment within aneurysmal tissue is likely to lessen aortic valve distortion
Adverse events

- **Endocarditis**
  - Rare cases of endocarditis have been reported
  - Considered a serious adverse event if unable to be cleared medically
  - Risk factors have been difficult to identify

- **Device embolization**
  - Considered to be 1-2% of cases
  - Can typically be retrieved via transcatheter methods
  - Rarely require surgical intervention
Patient selection

- Patient fulfillment of criteria for an intervention
  - Elevated Qp/Qs
  - Echocardiographic criteria for left heart volume overload
  - Failure to thrive
  - Congestive heart failure (poor weight gain/ increasing medical therapy)
  - Discussion with CT surgical staff
Defect identification

- Aneurysmal tissue or “windsock” appearance
- Defect location
  - Apical
  - Mid-muscular
  - Anterior/ posterior
  - Sub-aortic rim tissue amount
Summary

- Percutaneous/ periventricular occlusion of ventricular septal defects can be performed safely with a variety of occlusive devices.
- Currently, there is only one approved muscular VSD device in the United States.
- “Off-label” devices have been used to occlude ventricular septal defects.
- Complications can occur:
  - Heart block or conduction anomalies
  - Hemolysis
  - Device embolization
  - Aortic valve distortion