Perventricular Closure of Muscular VSD’s

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SCAI Fall Fellows Course, LV 2014
“Show me the Evidence....
Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith, Jill P Pell

Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials
A call to (broken) arms

Only two options exist. The first is that we accept that, under exceptional circumstances, common sense might be applied when considering the potential risks and benefits of interventions. The second is that we continue our quest for the holy grail of exclusively evidence based interventions and preclude parachute use outside the context of a properly conducted trial. The dependency we have created in our population may make recruitment of the unenlightened masses to such a trial difficult. If so, we feel assured that those who advocate evidence based medicine and criticise use of interventions that lack an evidence base will not hesitate to demonstrate their commitment by volunteering for a double blind, randomised, placebo controlled, crossover trial.
Historical Context

• Originally described – 1992 (Clamshell)

• Amplatzer device – Canine model 1999

• Perimembranous defects/PIVSD

• Numerous devices reported
  – Cardioseal
  – Lifetech
  – Shanghai Shape Memory Alloy Co
Indications

• Class IIb recommendation:
  “limitation of this approach for neonates or infants weighing less than 5 kgs with a hemodynamically significant muscular VSD undergoing surgery for concomitant defects requiring CPB (level of evidence B)”

(Circulation. 2011;123:2607-2652.)
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Procedure

• Location (OR vs Hybrid Lab vs Cath Lab)

• Collaboration
  • CV Surgery
  • Echocardiography

• Equipment
  • Hybrid sheath (Cordis (Brite Tip) 5.5cm with distal marker)
  • Muom sheath (Cook)
  • Echogenicity of wire used to cross
  • Appropriate device sizes
Procedure
Perventricular VSD Closure

A

RA  LA

RV  LV

C

RV  LV

B

D

The Society for Cardiovascular Angiography and Interventions

RUSH UNIVERSITY MEDICAL CENTER
Perventricular VSD Closure
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Perventricular VSD Closure
More Complex Cases
Multiple Defects – Cant Cross Again
Multiple Defects – Cross From RFA
Complex Defects – CoA with Multiple VSD’s – S/p ESA and PAB
Initial device – Pre CPB
Following CBP with VSD closure and Debanding
Crossing the Second Defect
Deployment of the Second Device

What Has Happened?
Complex Case – Heart Block with PH and Multiple VSD’s
Crossing the Defect
Deployment of First Device
Deployment of Second Device –
Weans off CPB
Most Recent Follow-up
Novel Reported Approaches
PDA Device for Apical Defects
PIVSD with Exteriorized ASO
Outcomes

• > 60 collective published attempted procedures
• Success rates of 85-100% and variable residual shunting rates.
• ~ 50% of these patients weighed 6 kgs or less
• Published data with PMVSD and DCSA VSD’s
Acute and Mid-Term Results Following Hybrid Perventricular Device Closure of Muscular Ventricular Septal Defects: A Multicenter PICES Investigation

Robert G Gray, Shaji C Menon, Joyce T Johnson, Aimee K Armstrong, Michael A Bingler, John P Breinholt III, Damien Kenny, John Lozier, Joshua J Murphy, Shyam K Sathanandam, Nathan W Taggart, Sara Trucco, Bryan H Goldstein, Brent M Gordon
Methods

- Retrospective, multicenter, cohort study
- **PICES** - Pediatric/congenital Interventional Cardiology Early career Society investigation
- 12 large US pediatric cardiology centers
- Inclusion criteria:
  - All patients who had an attempted perventricular device closure of a mVSD (hybrid procedure)
  - 1/2004 – 1/2014
- Core lab for echocardiographic studies (Utah)
- Procedure
  - Double-disc self-centering device
  - TEE ± fluoroscopic guidance

![Diagram of heart with a VSD and surgical procedure](image)
Simple VSD
Perventricular VSD Closure
Only

Complex VSD
Perventricular VSD Closure +
Concomitant Surgical Procedure

Eligible Patients
Results

N=47

Simple VSD: N=22

Complex VSD: N=25

81%
80%
20%
14%
7%

- Mid-muscular
- Apical
- "Swiss-cheese"
mVSD Closure Attempts by Site

![Bar chart showing mVSD closure attempts by site, with yellow indicating complex and blue indicating simple cases.]
Concomitant Surgery - Complex VSD (N=25)

- PAB takedown: 20%
- ASD/VSD ± PAB: 32%
- Arch ± PAB: 28%
- Complex: (TOF/TGA/CAVC/Other): 20%
# Demographics and Acute Outcomes

<table>
<thead>
<tr>
<th>Simple VSD (N=22)</th>
<th>Complex VSD (N=25)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at Surgery (mo)</td>
<td>5.3 (IQR 4.2-6.5)</td>
<td>5.2 (IQR 0.4-16.8)</td>
</tr>
<tr>
<td>Wt. at Surgery (kg)</td>
<td>5.1 (IQR 4.3-5.8)</td>
<td>5.1 (IQR 4.0-9.2)</td>
</tr>
<tr>
<td>VSD Size (mm)</td>
<td>9.5 ± 2.7</td>
<td>7.3 ± 2.7</td>
</tr>
<tr>
<td>Device Size (mm)</td>
<td>10 (range 6-16)</td>
<td>8 (range 4-14)</td>
</tr>
<tr>
<td>ICU LOS (days)</td>
<td>2 (IQR 1-3)</td>
<td>8.5 (IQR 2-15)</td>
</tr>
<tr>
<td>Hospital LOS (days)</td>
<td>4 (IQR 3-8)</td>
<td>14.5 (IQR 6-34)</td>
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**Procedural details**

- Performed in OR with TEE Guidance 91% (43/47)
- > 1 Device Placed 9% (4/47)
- ASA at D/C 90% (40/44)
Simple VSD - Outcomes

- Successful device deployment: 100% (22/22)
- Composite adverse outcome: 14% (3/22)
  - Significant residual VSD
  - Surgically repositioned
  - LV pseudoaneurysm
  - Mortality 0% (0/22)
- Minor adverse events 2
  - Short run of VT: Meds for 6 months (4.3 yrs. f/u)
  - Seizure post-op: No treatment or sequelae (2.8 yrs. f/u)
Complex VSD - Outcomes

- Successful device deployment: 80% (21/25)
- Composite adverse outcome: 28% (7/25)
  - Failed deployment N=4
    - Surgically closed (2)
    - CHB during device implant (2)
  - Significant residual VSD N=1
  - Device malposition N=1
  - LV Perforation by delivery sheath N=1
- Mortality/Tx: 16% (4/25)
  - Arch + mVSD – Died in OR (mucus plug)
  - D-TGA + mVSD – Died POD#155 (respiratory cause)
  - D-TGA + multiple VSDs – Died POD#24 (on ECMO)
  - CAVC + multiple VSDs + MV/LV hypoplasia – OHTx POD#70
Factors Associated with Hospital LOS  
Simple VSD (N=22)

<table>
<thead>
<tr>
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<th>Coefficient SEM (95% CI)</th>
<th>P Value</th>
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<tr>
<td>VSD size</td>
<td>0.6, 0.2 (0.077-1.05)</td>
<td>0.03</td>
</tr>
<tr>
<td>Composite adverse outcome</td>
<td>10.5, 2.0 (6.3-14.7)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

- Larger VSD size and presence of a composite adverse outcome is associated with longer length of stay
- No predictors of composite adverse outcome
- Site volume was not a predictor
Mid-term Follow-up (N=47)

- Follow-up 89% (42/47)
- Median Follow up 19.2 mos (IQR 2.3-43)
- Normal Functional Status (Class I) 90% (35/39)
- Re-interventions 8% (3/39)
  - Additional VSD percutaneous closures (4, 6wks Post-op)
  - LV pseudoaneurysm coil embolization (14 mos Post-op)
- ECG
  - No late heart block or arrhythmias
- Echo
  - >Mild MR/TR 0
  - >Mildly decreased RV/LV fxn 0
- Mortality on follow up 0% (0/39)
Conclusions

• Hybrid perventricular device closure of muscular VSDs
  • **Simple VSD**
    • Avoids CPB
    • High success rates and minimal complications
    • Short LOS
    • Low mortality
    • Low risk of arrhythmia, heart block, or ventricular dysfunction on mid-term follow-up
  • **Complex VSD**
    • High success rates and minimal complications
    • Outcomes are heavily influenced by
      • Patient complexity
      • Concomitant surgical procedures