PFO and ASD Closure

Mitul Patel, MD, FACC, FSCAI
Associate Clinical Professor of Medicine
Division of Cardiovascular Medicine
UC San Diego Sulpizio Cardiovascular Center
VA Medical Center San Diego
Disclosures

- Avinger - Consultant, Advisory Board
- Medicines Company - Speaker’s Bureau, Advisory Board
- Astra Zeneca - Speaker’s Bureau
- Abbott Vascular - Advisory Board
Patent Foramen Ovale
In 2002, the FDA approved via a Humanitarian Device Exemption (HDE) both the:
– CardioSeal Septal Occlusion System
– Amplatzer® Patent Foramen Ovale occluder

HDE is a category of FDA approval that is applicable to devices that are designed to treat a population of less than 4,000 patients per year.

This approval process requires the manufacturer to submit data on the safety and the probable clinical benefit.

Clinical trials validating the device effectiveness are not required with HDE.
The HDE led to a 50-fold increase in the use of PFO closure devices – Well in excess of 4,000 patients per year

In 2006, the FDA withdrew the HDE approval for these devices.

At this time, the FDA also reiterated the importance of randomized, controlled trials of PFO closure devices versus medical therapy, and noted that ongoing trials were hampered by slow enrollment.

Currently, all uses of closure devices to treat PFO are off-label uses or implanted under the investigational device exemption.
PFO - points to remember

• PFO’s are common in the general population

• PFO’s can be related to stroke - via paradoxical embolism or activation of platelets in the tunnel of the defect

• Not all PFO’s in stroke patients are pathogenic

• Not all PFO’s in cryptogenic stroke patients are pathogenic

• Closing incidental PFO’s will not offer benefit
### TABLE 3. Autopsy Prevalence of PFO

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Prevalence, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parsons and Keith[^40]</td>
<td>399</td>
<td>26</td>
</tr>
<tr>
<td>Fawcett and Blanchford[^41]</td>
<td>306</td>
<td>32</td>
</tr>
<tr>
<td>Scammon et al[^42]</td>
<td>809</td>
<td>29</td>
</tr>
<tr>
<td>Patten[^43]</td>
<td>4083</td>
<td>25</td>
</tr>
<tr>
<td>Seib[^44]</td>
<td>500</td>
<td>17</td>
</tr>
<tr>
<td>Wright et al[^45]</td>
<td>492</td>
<td>23</td>
</tr>
<tr>
<td>Schroekenstein et al[^46]</td>
<td>144</td>
<td>35</td>
</tr>
<tr>
<td>Sweeney and Rosenquist[^47]</td>
<td>64</td>
<td>31</td>
</tr>
<tr>
<td>Hagen[^48]</td>
<td>965</td>
<td>27</td>
</tr>
<tr>
<td>Thompson and Evans[^49]</td>
<td>1000</td>
<td>29</td>
</tr>
<tr>
<td>Penther[^50]</td>
<td>500</td>
<td>15</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>9262</strong></td>
<td><strong>26</strong></td>
</tr>
</tbody>
</table>
PFO Prevalence

- Stroke at age < 60
- No etiology identified
- Diagnosed with cryptogenic stroke
- PFO Prevalence is 40 - 60%

Webster, Lancet (1988) 2(8601):11
Lechat, NEJM (1988) 318:1148
Ranoux, Stroke (1993) 1:31
The Lausanne Study - Neurology (1996)
Comparison of Three Patent Foramen Ovale Closure Devices in a Randomized Trial (Amplatzer Versus CardioSEAL-STARflex Versus Helex Occluder)

Margaret Taaffe\textsuperscript{a}, Evelyn Fischer, MD\textsuperscript{b}, Andreas Baranowski\textsuperscript{a}, Nicolas Majunke\textsuperscript{a}, Corinna Heinisch\textsuperscript{a}, Michaela Leetz, MD\textsuperscript{a}, Ralph Hein, MD\textsuperscript{a}, Yves Bayard, MD\textsuperscript{a}, Franziska Büscheck, MD\textsuperscript{a}, Madlen Reschke, MD\textsuperscript{a}, Ilona Hoffmann, MD\textsuperscript{a}, Nina Wunderlich, MD\textsuperscript{a}, Neil Wilson, MD\textsuperscript{a}, and Horst Sievert, MD\textsuperscript{a,b,*}

- Compared procedural complications and 30-day clinical outcomes
- 660 patients (220 per group)
- All had paradoxical embolus
- 100% Technical success
- 7/220 Helex occluders had to be exchanged for 1 of the other devices whereas only 2/220 in other 2 groups had to be exchanged
- 3 device embolizations in the Helex group were retrieved and replaced
- 1 TIA and 1 hemopericardium in the Helex group
- 8/220 CardioSEAL-STARflex group had thrombi on device which resolved with anticoagulation
- 11/220 CardioSEAL-STARflex group had afib
Kaplan-Meier for Primary Endpoint ITT

A Prospective, Controlled Trial of the STARFlex® Umbrella with best medical therapy for patients with a Transient Ischemic Attack or a Paradoxical Embolism. 28mm, 33mm
PC Trial

- Approximately 400 patients
- Cryptogenic stroke
- Amplatzer vs. Med Rx
- 5 year follow-up
- Primary endpoint
  - Composite of:
    • Death
    • Non-fatal stroke
    • TIA
    • Peripheral embolism
Inclusion Criteria:
- Patients (ages 18 to 60) with PFO who have had a cryptogenic stroke within 270 days
- Stroke defined as acute focal neurological deficit, presumed to be due to focal ischemia, and either symptoms persisting 1) ≥ 24 hours, or 2) < 24 hours with MR or CT confirmed new, neuroanatomically relevant, cerebral infarct
- PFO defined as TEE visualization of micro-bubbles in the left atrium within 3 cardiac cycles of their appearance in the right atrium at rest and/or during Valsalva release

Key Exclusion Criteria:
- Cerebral, cardiovascular, and systemic conditions that suggest other mechanisms for stroke. Examples:
  - Carotid disease, atrial fibrillation, cardiomyopathy, etc
  - Arterial hypercoagulable states
  - Uncontrolled diabetes mellitus or hypertension
  - Other sources of right to left shunt

Contraindications:
- To aspirin or clopidogrel
- Anatomical to device placement

Any other reason to expect limited life expectancy, inability to attend follow-up visits, or inability to provide informed consent.
Primary and Secondary Endpoints

**Primary Endpoints**

- Recurrence of a nonfatal ischemic stroke or
- Fatal ischemic stroke or
- Early post-randomization death defined as all-cause mortality
  - Device group – within 30 days after implant or 45 days after randomization, whichever occurs latest
  - Medical group – within 45 days after randomization

**Secondary Endpoints**

- Complete closure of the defect demonstrated by transesophageal echocardiography (TEE) and bubble study at the 6-month follow-up (Device Group)
- Absence of recurrent symptomatic cryptogenic nonfatal stroke or cardiovascular death
- Absence of transient ischemic attack (TIA)

RESPECT Trial Design

Enrolled
N=980

Randomization stratified by site and presence/absence of atrial septal aneurysm

Randomized to device group
N = 499

Randomized to medical group
N = 481

Study device implant attempted
N = 464

Medical treatment specified pre-randomization by site neurologist

Post Implant: clopidogrel 1 month and aspirin 6 months. After 6 months, antiplatelet therapy at discretion of site investigator

TEE with bubble study at 6 months

Aspirin only 46.5%
Warfarin only 25.2%
Clopidogrel only 14.0%
Aspirin + dipyridamole 8.1%
Aspirin + clopidogrel 6.2%

1. Aspirin + clopidogrel was removed from the protocol in 2006 based on changes to the AHA/ASA treatment guidelines

Respect Trial

The 25 adjudicated endpoint events
*All primary endpoints were recurrent ischemic strokes. No study related deaths*

Analytic data set: observational period from the beginning of the trial to the date when the 25th primary endpoint event was adjudicated

Number Needed to Treat

<table>
<thead>
<tr>
<th></th>
<th>NNT$^2$</th>
<th>Device Group Event Rate$^3$</th>
<th>Medical Group Event Rate$^3$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Year</td>
<td>250</td>
<td>1.33%</td>
<td>1.73%</td>
</tr>
<tr>
<td>2 Year</td>
<td>70.4</td>
<td>1.60%</td>
<td>3.02%</td>
</tr>
<tr>
<td>5 Year</td>
<td>23.9</td>
<td>2.21%</td>
<td>6.40%</td>
</tr>
</tbody>
</table>

1. P-values:ITT Raw Count is calculated using Fisher’s Exact test; all other P-values are calculated using log-rank test.
2. The NNT is the average number of subjects that need to be treated with the AMPLATZER™ PFO Occluder in order to prevent one stroke in the respective time intervals. The NNT is calculated as the reciprocal of the difference between the control arm and device arm event rates.
3. Calculated using the Kaplan-Meier estimated event rates for each treatment group.

## Subpopulation Differential Treatment Effect

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Device Group</th>
<th>Medical Group</th>
<th>Hazard Ratio and 95% CI</th>
<th>Pvalue (Log Rank)</th>
<th>Interaction Pvalue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>9/499 (1.8%)</td>
<td>16/481 (3.3%)</td>
<td>0.492 (0.217, 1.114)</td>
<td>0.0825</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.5156</td>
</tr>
<tr>
<td>- 18-45</td>
<td>4/230 (1.7%)</td>
<td>5/210 (2.4%)</td>
<td>0.698 (0.187, 2.601)</td>
<td>0.5901</td>
<td></td>
</tr>
<tr>
<td>- 46-60</td>
<td>5/262 (1.9%)</td>
<td>11/266 (4.1%)</td>
<td>0.405 (0.140, 1.165)</td>
<td>0.0828</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.7312</td>
</tr>
<tr>
<td>- Male</td>
<td>5/268 (1.9%)</td>
<td>10/268 (3.7%)</td>
<td>0.448 (0.153, 1.311)</td>
<td>0.1321</td>
<td></td>
</tr>
<tr>
<td>- Female</td>
<td>4/231 (1.7%)</td>
<td>6/213 (2.8%)</td>
<td>0.571 (0.161, 2.024)</td>
<td>0.3789</td>
<td></td>
</tr>
<tr>
<td>Shunt Size</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.0667</td>
</tr>
<tr>
<td>- None, trace or moderate</td>
<td>7/247 (2.8%)</td>
<td>6/244 (2.5%)</td>
<td>1.034 (0.347, 3.081)</td>
<td>0.9527</td>
<td></td>
</tr>
<tr>
<td>- Substantial</td>
<td>2/247 (0.8%)</td>
<td>10/231 (4.3%)</td>
<td>0.178 (0.039, 0.813)</td>
<td>0.0119</td>
<td></td>
</tr>
<tr>
<td>Atrial septal aneurysm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.1016</td>
</tr>
<tr>
<td>- Present</td>
<td>2/180 (1.1%)</td>
<td>9/169 (5.3%)</td>
<td>0.187 (0.040, 0.867)</td>
<td>0.0163</td>
<td></td>
</tr>
<tr>
<td>- Absent</td>
<td>7/319 (2.2%)</td>
<td>7/312 (2.2%)</td>
<td>0.889 (0.312, 2.535)</td>
<td>0.8259</td>
<td></td>
</tr>
<tr>
<td>Index infarct topography</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.3916</td>
</tr>
<tr>
<td>- Superficial</td>
<td>5/280 (1.8%)</td>
<td>12/269 (4.5%)</td>
<td>0.366 (0.129, 1.038)</td>
<td>0.0487</td>
<td></td>
</tr>
<tr>
<td>- Small Deep</td>
<td>2/57 (3.5%)</td>
<td>1/70 (1.4%)</td>
<td>1.762 (0.156, 19.93)</td>
<td>0.6429</td>
<td></td>
</tr>
<tr>
<td>- Other</td>
<td>2/157 (1.3%)</td>
<td>3/139 (2.2%)</td>
<td>0.558 (0.093, 3.340)</td>
<td>0.5167</td>
<td></td>
</tr>
<tr>
<td>Planned medical regimen</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.1966</td>
</tr>
<tr>
<td>- Anticoagulant</td>
<td>4/132 (3.0%)</td>
<td>3/121 (2.5%)</td>
<td>1.141 (0.255, 5.098)</td>
<td>0.8628</td>
<td></td>
</tr>
<tr>
<td>- Antiplatelet</td>
<td>5/367 (1.4%)</td>
<td>13/359 (3.6%)</td>
<td>0.336 (0.120, 0.944)</td>
<td>0.0299</td>
<td></td>
</tr>
</tbody>
</table>
Significant Reduction in Recurrent Cryptogenic Stroke
54% Relative Risk Reduction in ITT Population

Event-free Probability

- **AMPLATZER™ PFO Occluder**
  (N=499; # cryptogenic strokes = 10)

- **Medical Management**
  (N=481; # cryptogenic strokes = 19)

- Device not in place

HR: 0.460
Log-rank p-value: 0.042

# at Risk (KM Estimates)

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>AMPLATZER</strong></td>
<td>499(0%)</td>
<td>463 (1.2%)</td>
<td>369 (1.5%)</td>
<td>212 (2.5%)</td>
<td>86 (2.5%)</td>
<td>20 (2.5%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>MM</strong></td>
<td>481(0%)</td>
<td>394 (2.7%)</td>
<td>307 (4.1%)</td>
<td>168 (4.1%)</td>
<td>71 (5.2%)</td>
<td>10 (10.8%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Ongoing PFO Closure Trials

- **CLOSE** - European study of any CE approved closure device vs. Medical Rx with ASA or Vit K antagonist
  - Should complete enrollment Dec 2016

- **REDUCE** - Gore Helex Septal Occluder + antiplatelet Rx vs. Antiplatelet Rx alone
  - No results available
Patient Selection

Tedy Bruschi - former linebacker for the New England Patriots

There's a hole in my heart that can only be filled by Bru-schi.
Atrial Septal Defects
Secundum Atrial Septal Defect

Nonoperative Closure During Cardiac Catheterization

Terry D. King, MD; Sandra L. Thompson, RN; Charles Steiner, MD; Noel L. Mills, MD

Fig 1.—Outer catheter in capsule (top left) with an internal right atrial umbrella catheter with distal threads and containing obturator wire. Opened left atrial umbrella (lower, left) and opened right atrial umbrella (lower, right).

Fig 4.—Overpenetrated roentgenogram. Arrows indicate paired, opposed, locked umbrellas within heart.

(JAMA 235:2506-2509, 1976)
Anatomy

From: Eidem BW, ed. Echocardiography in Pediatric and Adult Congenital Heart Disease
Prevalence in Adulthood

- 30-40% of congenital heart defects in adults
- Types of ASD
  - Secundum - 70%
  - Primum - 20%
  - Sinus Venosus - 10%
  - Coronary Sinus - < 1%
Associated Anomalies with Specific ASDs

- Cleft mitral valve, northwest axis on EKG:
  - Primum ASD
- Anomalous pulmonary veins:
  - Sinus Venosus ASD
- Left SVC:
  - Coronary Sinus ASD
Hemodynamics and Exam

- Direction of shunt flow dependent on ventricular compliance
  - LV diastolic dysfunction more prominent in older adults
- Systolic murmur - from increased blood flow across the pulmonic valve
- Diastolic murmur - from increased blood flow across the tricuspid valve
- Fixed split S2
Natural History

• Relatively benign in childhood
  – usually well tolerated in infancy
  – spontaneous closure is possible
    • < 6mm ~ 80%  >8mm ~ 0%
  – Enlargement also possible
  – Usually if < 5mm and no e/o RV volume overload - no impact on natural history of individual thus do not close unless patient has paradoxical embolus

• Secondary effects - usually in 3rd decade
  – Heart - atrial arrhythmias, exercise tolerance, TR, CHF
  – Lungs - PAH

• Defects < 10mm (small) may present much later in life - with the development of diastolic dysfunction
Long Term Complications

• RV failure or dilation, TR

• Pulmonary hypertension

• Atrial arrhythmias
  – Repair before age 25, excellent prognosis
  – After age 40, increased risk of arrhythmias remains
ACC/AHA Guidelines

- **Class I**

1. Closure of an ASD either percutaneously or surgically is indicated for right atrial and RV enlargement with or without symptoms. *(Level of Evidence: B)*

2. A sinus venosus, coronary sinus, or primum ASD should be repaired surgically rather than by percutaneous closure. *(Level of Evidence: B)*

3. Surgeons with training and expertise in CHD should perform operations for various ASD closures. *(Level of Evidence: C)*
ACC/AHA Guidelines

• Class IIa

• 1. Surgical closure of secundum ASD is reasonable when concomitant surgical repair/replacement of a tricuspid valve is considered or when the anatomy of the defect precludes the use of a percutaneous device. \(\text{(Level of Evidence: C)}\)

• 2. Closure of an ASD, either percutaneously or surgically, is reasonable in the presence of:
  ◦ a. Paradoxical embolism. \(\text{(Level of Evidence: C)}\)
  ◦ b. Documented orthodeoxia-platypnea. \(\text{(Level of Evidence: B)}\)
Transesophageal echocardiogram in supine and sitting positions.


Copyright © American Heart Association
ACC/AHA Guidelines

• **Class IIb**

1. Closure of an ASD, either percutaneously or surgically, may be considered in the presence of net left-to-right shunting, pulmonary artery pressure less than two thirds systemic levels, PVR less than two thirds systemic vascular resistance, or when responsive to either pulmonary vasodilator therapy or test occlusion of the defect (patients should be treated in conjunction with providers who have expertise in the management of pulmonary hypertensive syndromes). *(Level of Evidence: C)*

2. Concomitant Maze procedure may be considered for intermittent or chronic atrial tachyarrhythmias in adults with ASDs. *(Level of Evidence: C)*

• **Class III**

1. Patients with severe irreversible PAH and no evidence of a left-to-right shunt should not undergo ASD closure. *(Level of Evidence: B)*
Practical Guidelines

- Qp:Qs > 1.5:1
- Defect > 10mm
- PVR < 7 WU
- Be careful with elevated LVEDP
  - may need diuretic therapy after closure
- For PVR > 7 WU and PA pressures > 50% systemic, need to perform O2 and NO study
FDA Approved Devices for Secundum ASD Closure

- GORE HELEX™ Septal Occluder

- AMPLATZER™ Septal Occluder (St. Jude)
Comparison Between Transcatheter and Surgical Closure of Secundum Atrial Septal Defect in Children and Adults
Results of a Multicenter Nonrandomized Trial
Zhong-Dong Du, MD,* Ziyad M. Hijazi, MD, MPH, FACC,* Charles S. Kleinman, MD, FACC,† Norman H. Silverman, MD, FACC,‡ Kinley Lamztz, PhD,§ for the Amplatzer Investigators
Chicago, Illinois; Orlando, Florida; San Francisco, California; and Minneapolis, Minnesota

*San Diego Sulpizio Cardiovascular Center

Results

![Graph showing probability of freedom from complication over follow-up time for Device and Surgical groups. The graph indicates a statistically significant difference (P<0.001) between the two groups.]

Sizing the Device

• Diameter of waist corresponds to “stretched” diameter
  – determined by sizing balloon

• Waist diameters range from 4 to 40mm
  – 4-10mm
    • LA disc is 12mm larger than waist
    • RA disc is 8mm larger than waist
  – 11-30mm
    • LA disc 14mm larger
    • RA disc 10mm larger
  – 32-40mm
    • LA disc 16mm larger
    • RA disc 10mm larger
<table>
<thead>
<tr>
<th>ASO Order Numbers</th>
<th>Device Size or Waist Diameter (mm)</th>
<th>RA Disc Diameter (mm)</th>
<th>Waist Width (mm)</th>
<th>LA Disc Diameter (mm)</th>
<th>RECOMMENDED SHEATH SIZE</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-ASD-004</td>
<td>4</td>
<td>12</td>
<td>3</td>
<td>16</td>
<td>6; 45°</td>
</tr>
<tr>
<td>9-ASD-005</td>
<td>5</td>
<td>13</td>
<td>3</td>
<td>17</td>
<td>6; 45°</td>
</tr>
<tr>
<td>9-ASD-006</td>
<td>6</td>
<td>14</td>
<td>3</td>
<td>18</td>
<td>6; 45°</td>
</tr>
<tr>
<td>9-ASD-007</td>
<td>7</td>
<td>15</td>
<td>3</td>
<td>19</td>
<td>6; 45°</td>
</tr>
<tr>
<td>9-ASD-008</td>
<td>8</td>
<td>16</td>
<td>3</td>
<td>20</td>
<td>6; 45°</td>
</tr>
<tr>
<td>9-ASD-009</td>
<td>9</td>
<td>17</td>
<td>3</td>
<td>21</td>
<td>6; 45°</td>
</tr>
<tr>
<td>9-ASD-010</td>
<td>10</td>
<td>18</td>
<td>3</td>
<td>22</td>
<td>6; 45°</td>
</tr>
<tr>
<td>9-ASD-011</td>
<td>11</td>
<td>21</td>
<td>4</td>
<td>23</td>
<td>7; 45°</td>
</tr>
<tr>
<td>9-ASD-012</td>
<td>12</td>
<td>22</td>
<td>4</td>
<td>24</td>
<td>7; 45°</td>
</tr>
<tr>
<td>9-ASD-013</td>
<td>13</td>
<td>23</td>
<td>4</td>
<td>27</td>
<td>7; 45°</td>
</tr>
<tr>
<td>9-ASD-014</td>
<td>14</td>
<td>24</td>
<td>4</td>
<td>28</td>
<td>7; 45°</td>
</tr>
<tr>
<td>9-ASD-015</td>
<td>15</td>
<td>25</td>
<td>4</td>
<td>29</td>
<td>7; 45°</td>
</tr>
<tr>
<td>9-ASD-016</td>
<td>16</td>
<td>26</td>
<td>4</td>
<td>30</td>
<td>7; 45°</td>
</tr>
<tr>
<td>9-ASD-017</td>
<td>17</td>
<td>27</td>
<td>4</td>
<td>31</td>
<td>7; 45°</td>
</tr>
<tr>
<td>9-ASD-018</td>
<td>18</td>
<td>28</td>
<td>4</td>
<td>32</td>
<td>8; 45°</td>
</tr>
<tr>
<td>9-ASD-019</td>
<td>19</td>
<td>29</td>
<td>4</td>
<td>33</td>
<td>8; 45°</td>
</tr>
<tr>
<td>9-ASD-020</td>
<td>20</td>
<td>30</td>
<td>4</td>
<td>34</td>
<td>9; 45°</td>
</tr>
<tr>
<td>9-ASD-022</td>
<td>22</td>
<td>32</td>
<td>4</td>
<td>36</td>
<td>9; 45°</td>
</tr>
<tr>
<td>9-ASD-024</td>
<td>24</td>
<td>34</td>
<td>4</td>
<td>38</td>
<td>9; 45°</td>
</tr>
<tr>
<td>9-ASD-026</td>
<td>26</td>
<td>36</td>
<td>4</td>
<td>40</td>
<td>10; 45°</td>
</tr>
<tr>
<td>9-ASD-028</td>
<td>28</td>
<td>38</td>
<td>4</td>
<td>42</td>
<td>10; 45°</td>
</tr>
<tr>
<td>9-ASD-030</td>
<td>30</td>
<td>40</td>
<td>4</td>
<td>44</td>
<td>10; 45°</td>
</tr>
<tr>
<td>9-ASD-032</td>
<td>32</td>
<td>42</td>
<td>4</td>
<td>46</td>
<td>12; 45°</td>
</tr>
<tr>
<td>9-ASD-034</td>
<td>34</td>
<td>44</td>
<td>4</td>
<td>50</td>
<td>12; 45°</td>
</tr>
<tr>
<td>9-ASD-036</td>
<td>36</td>
<td>46</td>
<td>4</td>
<td>52</td>
<td>12; 45°</td>
</tr>
<tr>
<td>9-ASD-038</td>
<td>38</td>
<td>48</td>
<td>4</td>
<td>54</td>
<td>12; 45°</td>
</tr>
</tbody>
</table>

Minimum Recommended Sheath Size: AMPLATZER Torque Delivery System (Fr.3 Curve)
Erosion of Amplatzer Septal Occluder Device After Closure of Secundum Atrial Septal Defects: Review of Registry of Complications and Recommendations to Minimize Future Risk

Zahid Amin,1‡ MD, Ziyad M. Hijazi,2‡ MD, John L. Bass,3‡ MD, John P. Cheatham,4‡ MD, William E. Hellenbrand,5 MD, and Charles S. Kleinman,5‡ MD
<table>
<thead>
<tr>
<th>Patient</th>
<th>Sex</th>
<th>Age (years)</th>
<th>Time to symptoms (days)</th>
<th>Pericardial tamponade</th>
<th>Intervention</th>
<th>ASD size (mm)</th>
<th>Stretched size (mm)</th>
<th>Device size (mm)</th>
<th>Deficient rim(s)</th>
<th>Perforation site</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>5</td>
<td>1</td>
<td>Yes</td>
<td>PC</td>
<td>11</td>
<td>16</td>
<td>16</td>
<td>Aortic</td>
<td>Unknown</td>
</tr>
<tr>
<td>2</td>
<td>M</td>
<td>8</td>
<td>1</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>10</td>
<td>20</td>
<td>20</td>
<td>Aortic</td>
<td>RA roof/aorta</td>
</tr>
<tr>
<td>3</td>
<td>M</td>
<td>8</td>
<td>1</td>
<td>Yes</td>
<td>S, PR,NR</td>
<td>11</td>
<td>18</td>
<td>18</td>
<td>Aortic</td>
<td>LA roof</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>10</td>
<td>1</td>
<td>Yes</td>
<td>PC</td>
<td>NR</td>
<td>12</td>
<td>14</td>
<td>Superior/aortic</td>
<td>Unknown</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>22</td>
<td>1</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>15</td>
<td>21</td>
<td>24</td>
<td>Aortic</td>
<td>RA roof/aorta</td>
</tr>
<tr>
<td>6</td>
<td>F</td>
<td>31</td>
<td>1</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>17</td>
<td>28</td>
<td>28</td>
<td>Unknown</td>
<td>LA/aorta</td>
</tr>
<tr>
<td>7</td>
<td>F</td>
<td>38</td>
<td>1</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>16</td>
<td>26</td>
<td>26</td>
<td>Aortic?</td>
<td>LA roof</td>
</tr>
<tr>
<td>8</td>
<td>F</td>
<td>40</td>
<td>1</td>
<td>Yes</td>
<td>PC</td>
<td>14</td>
<td>31</td>
<td>30</td>
<td>Aortic</td>
<td>LA roof/aorta</td>
</tr>
<tr>
<td>9</td>
<td>F</td>
<td>40</td>
<td>1</td>
<td>Yes</td>
<td>NS</td>
<td>29</td>
<td>32</td>
<td>36</td>
<td>Aortic</td>
<td>RUPV</td>
</tr>
<tr>
<td>10</td>
<td>M</td>
<td>53</td>
<td>1</td>
<td>No</td>
<td>NS</td>
<td>26</td>
<td>34</td>
<td>34</td>
<td>Aortic</td>
<td>Unknown</td>
</tr>
<tr>
<td>11</td>
<td>F</td>
<td>4</td>
<td>2</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>14</td>
<td>19</td>
<td>20</td>
<td>Aortic</td>
<td>LA roof/aorta</td>
</tr>
<tr>
<td>12</td>
<td>M</td>
<td>4</td>
<td>2</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>19</td>
<td>17</td>
<td>17</td>
<td>Superior/aortic</td>
<td>LA roof/aorta</td>
</tr>
<tr>
<td>13</td>
<td>F</td>
<td>24</td>
<td>2</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>13</td>
<td>16</td>
<td>18</td>
<td>Superior/aortic</td>
<td>RA roof/aorta</td>
</tr>
<tr>
<td>14</td>
<td>F</td>
<td>10</td>
<td>2</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>14</td>
<td>18</td>
<td>20</td>
<td>Superior</td>
<td>RA roof</td>
</tr>
<tr>
<td>15</td>
<td>F</td>
<td>16</td>
<td>2</td>
<td>No</td>
<td>NS</td>
<td>LC</td>
<td>LC</td>
<td>26</td>
<td>Superior/aortic</td>
<td>None</td>
</tr>
<tr>
<td>16</td>
<td>F</td>
<td>32</td>
<td>2</td>
<td>Yes</td>
<td>PC</td>
<td>NR</td>
<td>24</td>
<td>28</td>
<td>Unknown</td>
<td>No</td>
</tr>
<tr>
<td>17</td>
<td>F</td>
<td>36</td>
<td>2</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>27</td>
<td>34</td>
<td>38</td>
<td>Aortic</td>
<td>RA roof/aorta</td>
</tr>
<tr>
<td>18</td>
<td>F</td>
<td>22</td>
<td>3</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>18</td>
<td>NR</td>
<td>26</td>
<td>Aortic</td>
<td>LA roof/aorta</td>
</tr>
<tr>
<td>19</td>
<td>F</td>
<td>42</td>
<td>3</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>12</td>
<td>17</td>
<td>20</td>
<td>Aortic</td>
<td>LA/RA roof</td>
</tr>
<tr>
<td>20</td>
<td>F</td>
<td>18</td>
<td>21</td>
<td>No</td>
<td>S, PR,DR</td>
<td>24</td>
<td>25</td>
<td>26</td>
<td>Superior/aortic</td>
<td>Fistula to LA</td>
</tr>
<tr>
<td>21</td>
<td>F</td>
<td>59</td>
<td>30</td>
<td>Yes</td>
<td>S, PR,NR</td>
<td>19</td>
<td>22</td>
<td>22</td>
<td>Superior/aortic</td>
<td>LA roof</td>
</tr>
<tr>
<td>22</td>
<td>M</td>
<td>10</td>
<td>90</td>
<td>No</td>
<td>S, PR,DR</td>
<td>18</td>
<td>26</td>
<td>26</td>
<td>Aortic</td>
<td>Fistula to RA</td>
</tr>
<tr>
<td>23</td>
<td>F</td>
<td>31</td>
<td>90</td>
<td>Yes</td>
<td>S, PR,NR</td>
<td>12</td>
<td>19</td>
<td>22</td>
<td>Superior/aortic</td>
<td>LA roof</td>
</tr>
<tr>
<td>24</td>
<td>F</td>
<td>40</td>
<td>90</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>22</td>
<td>32</td>
<td>34</td>
<td>Aortic</td>
<td>LA roof</td>
</tr>
<tr>
<td>25</td>
<td>F</td>
<td>17</td>
<td>180</td>
<td>No</td>
<td>S, PR,DR</td>
<td>26</td>
<td>25</td>
<td>30</td>
<td>Aortic</td>
<td>Fistula to LA</td>
</tr>
<tr>
<td>26</td>
<td>F</td>
<td>42</td>
<td>180</td>
<td>Yes</td>
<td>S, PR,NR</td>
<td>9</td>
<td>12</td>
<td>14</td>
<td>Aortic</td>
<td>LA roof</td>
</tr>
<tr>
<td>27</td>
<td>M</td>
<td>23</td>
<td>240</td>
<td>Yes</td>
<td>S, PR,DR</td>
<td>13</td>
<td>23</td>
<td>26</td>
<td>Aortic</td>
<td>RA roof/aorta</td>
</tr>
<tr>
<td>28</td>
<td>F</td>
<td>49</td>
<td>1,095</td>
<td>Yes</td>
<td>NS</td>
<td>NR</td>
<td>19</td>
<td>24</td>
<td>Unknown</td>
<td>LA roof/aorta</td>
</tr>
</tbody>
</table>

*M, male; F, female; S, surgery; FR, fistula repaired; PR, perforation repaired; DR, device removed; NR, device not removed; NS, no intervention; PC, pericardiocentesis only; NR, not reported; LA, left atrium; RA, right atrium; RUPV, right upper pulmonary vein.
18mm Amplatzer Septal Occluder
Thank You

Where discoveries are delivered.™