Device Closure of ASD in Children – Using the Amplatzer Devices: Indications and catheter preparations, technique, and outcome

SCAI Fellow Course – Fall 2014

Ralf J Holzer MD MSc FSCAI
Medical Director
Cardiac Catheterization & Interventional Therapy
Interim Division Chief
Sidra Cardiovascular Center of Excellence
Atrial Septal Defect (ASD)

- Sinus venosus type
- Secundum type
- Primum type
Atrial Septal Defect (ASD)

- **Definition:**
  - Any opening in the atrial septum, other than a competent PFO

- **Types:**
  - **Secundum ASD:**
    - Interatrial communication in the region of the fossa ovalis
  - **Primum ASD:**
    - Defect caudal to the fossa ovalis
    - Defect of endocardial tissue development
    - Often associated with a cleft anterior MV leaflet
  - **Sinus venosus ASD:**
    - Posterior to the fossa ovalis
    - Often abnormal connection of the RPV to SVC or IVC
  - **Coronary sinus ASD:**
    - Failure of development of wall between CS and LA-unroofed CS
    - L-SVC usually present
Secundum ASD

Defect of the septum primum
• 0.1-0.5 per 1,000 life births
• 6 to 10% of all cardiac anomalies
• About 70% of all ASDs
• F:M= 2:1
• Usual sporadic
• Genetics:
  • Familial ASD could be caused by a gene mutation on chromosome 5p
  • Holt and Oram syndrome (ASD + upper limb abnormalities, autosomal dominant)
Secundum ASD

Definition:

- “Defect within the fossa ovalis”
  = deficiency in septum primum
  - insufficient overlap of “flap valve”
  - perforation of septum primum
  - absence of septum primum
Secundum ASD
ASD Physiology / Natural History

• Left to Right shunt
  • Increased in presence of LVOTO, LV inflow obstruction, or LV diastolic dysfunction

• Increase pulmonary blood flow

• Most infants with isolated ASDs are asymptomatic – symptoms rare before 2nd/3rd decade of life

• PA pressure is mildly increased and PVR remains normal in most cases-especially in first decade of life
ASD Physiology / Natural History

Problems do occur:

• RV / RA dilation

• Atrial arrhythmias:
  • Incidence increase with age and defect size
  • 11% in patients with Qp:Qs <2:1 vs 38% in pts with shunt >3:1

• Right heart failure

• Pulmonary Hypertension
  • 5-10% of untreated ASD
  • incidence increases with age
  • Female > male
  • More common in pts living at higher altitude
ASD Physiology / Natural History

- Reduced life expectancy (mean 37 - 49 years)
  - Likely an overestimate due to selection bias
    - Campbell, M. *Natural History of ASD* Br Heart Journal 1970;32:820-26
    - Dalen JE. et al *Life Expectancy with ASD* JAMA 1967;=200:442-6
    - Craig, RJ. *Nat History and Prognosis of ASD* Circ 1968;37:805-15
    - Haworth SG. *Pulm Vasc Disease in secundum ASD in childhood* AJC 1982;51:265-72
Recommendations for Transcatheter Device Closure of Secundum ASD

**Class I**

Transcatheter secundum ASD closure is indicated in patients with hemodynamically significant ASD with suitable anatomic features (*Level of Evidence: B*).

**Class IIa**

It is reasonable to perform transcatheter secundum ASD closure in patients with transient right-to-left shunting at the atrial level who have experienced sequelae of paradoxical emboli such as stroke or recurrent transient ischemic attack (*Level of Evidence: B*).

It is reasonable to perform transcatheter secundum ASD closure in patients with transient right-to-left shunting at the atrial level who are symptomatic because of cyanosis and who do not require such a communication to maintain adequate cardiac output (*Level of Evidence: B*).

**Class IIb**

Transcatheter closure may be considered in patients with a small secundum ASD who are believed to be at risk of thromboembolic events (eg, patients with a transvenous pacing system or chronically indwelling intravenous catheters, patients with hypercoagulable states) (*Level of Evidence: C*).
Recommendations for Transcatheter Device Closure of Secundum ASD

**Class III**

Transcatheter secundum ASD closure is not indicated in patients with a small secundum ASD of no hemodynamic significance and with no other risk factors *(Level of Evidence: B)*.

Transcatheter ASD closure should not be performed with currently available devices in patients with ASDs other than those of the secundum variety. This would include defects of septum primum, sinus venosus defects, and unroofed coronary sinus defects *(Level of Evidence: C)*.

Transcatheter ASD closure is contraindicated in the management of patients with a secundum ASD and advanced pulmonary vascular obstructive disease *(Level of Evidence: C)*.
Treatment Options

Surgery…..60+ years and counting


Gross RE. Surgical Closure of defects in the interatrial septum by use of an atrial well. N. Engl J Med 1952; 247:455-8


Numerous published surgical series since then
  – Low mortality and steadily decreasing morbidity
Transcatheter closure

King T, Mills N. Nonoperative closure of atrial septal defects. 1974; 75:383-88
- Initially attempted in adult dogs

Work expanded to human patients
- Mills N, King T. Nonoperative closure of left-to-right shunts JTCVS. 1976; 72:371-78
- 18 pts / 10 deemed suitable / 5 successfully closed

Device = paired, Dacron covered stainless steel “umbrellas”
- 22-23 F complicated delivery system ………therefore didn’t catch on
- However, device recognized as the first “double umbrella”
William Rashkind, MD

Concomitantly developed the **Rashkind Atrial Septal Defect Occluder**

Rashkind WJ *Experimental transvenous closure of ASD + VSD* Circ 1975;52:2-8

Rashkind WJ *TCC of ASD in children* Eur J Cardiol 1977;8:119-20

- Single disk anchored by “fish hooks”
- 14-16f delivery sheath
- 25, 30 and 35mm
Lock Clamshell Occluder
CardioSEAL device
  - 2nd generation Clamshell
STARFlex device
  -
ASD Closure Devices

• FDA-Approved devices:
  • Amplatzer Septal Occluder (AGA)
  • Amplatzer Cribriform Septal Occluder (AGA)
  • HELEX Septal Occluder (Gore)

• Other devices (current and historical):
  • Figulla ASD Occluder (Occlutech)
  • AtriaSept ASD Device (CARDIA)
  • BioSTAR - Bioabsorbable Septal Repair Implant (NMT)
  • Sideris Buttoned Device
  • ASDOS
  • DAS Angel Wings
  • Transcatheter Patch
Amplatzer Septal Occluder

Amplatzer, K et al Transvenous closure of secundum ASD. Prelim Results a New self expanding nitinol prosthesis in a Swine model Circ 1997;95:2162-8

Amplatzer device first implanted in humans, September 1995

Amplatzer Septal Occluder (AGA)

• Self-expandable, double disc device made from Nitinol wire mesh
• 2 discs linked by a short connecting waist corresponding to the size of the ASD
• Available in sizes 4 to 40 mm (approved up to 38 mm in US)
• Device selection is based on the 'stop-flow' diameter of the defect (as assessed by TEE/ICE)
• Closure rate at 1 year >95%
• 6Fr – 12Fr Delivery system
Amplatzer Atrial Septal Occluder (ASO)
Amplatzer Cribriform Septal Occluder

- Closure of ASDs with multiple perforations commonly associated with septal aneurysm
- The two discs are linked together by a short (3mm) connecting waist
- Available in 18, 25, 30, 35mm
- 8-9Fr Delivery system
- Pick the central defect
Suitability for Transcatheter Device Closure

Necessary ECHO measurements

Defect size from multiple views (SC frontal, and SC sagital, parasternal short axis, apical 4C)

Total Septal length

Rims:
- Mitral Valve (apical 4c)
- Aortic (PS short)
- SVC / pulmonary veins

Fig. 1. Classification of atrial septal rims.
ASO Procedure

Step 1: (after history and PEx) ECHO Assessment

Step 2: TEE or ICE imaging

Step 3: Hemodynamic assessment
  • venous access - 8Fr sheath (+/- Arterial line)
  • Right heart cath
    » qp:qs; pvr etc

Step 4: Balloon size and device selection
  » “stop flow” waist +/- 0-2 mm

Step 5: Load device, advance across ASD and open (may need to pull up TEE probe)

Step 6: Assess by ECHO and “Wiggle”

Step 7: release and reassess
Amplatzer Device Case example
Amplatzer Device
Balloon sizing

“Stop Flow” technique
Minnesota Wiggle
ASO release
ASO post TEE
ASO post CXR

Amplatzer Device
The difficult ASO deployment – there is help!

Second venous catheter to prevent device from pulling through
Hausdorf sheath
Steerable sheath
Pulmonary vein deployment
Pull up TEE probe
Deploy entire device in LA and then recapture RA disk
Up-or down size device
ASD Closure – pulmonary vein deployment
Multiple ASDs

Gianfranco Butera,1* MD, PhD, FSCAI, Enrico Romagnoli,1 MD, Zakhia Saliba,2 MD, Massimo Chessa,1 MD, PhD, FSCAI, Giuseppe Sangiorgi,3 MD, FSCAI, Alessandro Giamberti,1 MD, Riccardo Cappato,4 MD, Claudio Bussadori,1 MD, Raul Abella,1 MD, Gabriele Pelissero,1 MD, Alessandro Frigiola,1 MD, and Mario Carminati,1 MD, FSCAI

Results: Multiple device implantations were required in 47% of cases, especially in patients with d-ASD and c-ASD. Complication rate, residual shunt, and long term outcome were comparable among the four different categories. In particular, at long term follow-up (6 ± 2 years) no patient required further surgical or percutaneous treatment and complete closure was confirmed in 99% of cases. Conclusions: Percutaneous closure of multiple ASDs is feasible and associated with a good outcome. A thorough identification and analysis of morphological aspects are mandatory in order to select the appropriate device and the optimal strategy. © 2010 Wiley-Liss, Inc.
The challenging access
ASO Outcomes

The ASO pivotal study:

March 1998 to March 2000 ➔ FDA approval December 2001

multicenter nonrandomized

- 29 pediatric cardiology centers from
- 442 patients enrolled in the device group
- 154 patients in the surgical group.

Compare the safety, efficacy, and utility of the ASO to surgical closure.

complication rate:

- 7.2% for the device group
- 24% for the surgical group
- mortality = 0% for both groups
The early, primary and secondary efficacy success rates for surgical versus device closure of ASD were not statistically different.

The complication rate was lower and the length of hospital stay was shorter for device closure when compared to surgical repair.

Appropriate patient selection is an important factor for successful device closure.

Du et al, Journal of the American College of Cardiology, 2002
ASO Outcomes

Numerous early and intermediate reports following pivotal trial

- ALL SHOW EQUIVALENT SUCCESS RATES (>95% complete closure)
- ALL SHOW LOWER COMPLICATION RATES for TCC
- ALL SHOW SHORTER HOSPITAL LOS

Now starting to see long term results (approx 15-16 years)

A success story, but unresolved issues remain, especially concerning erosion
Long-Term Outcome of Transcatheter Secundum-Type Atrial Septal Defect Closure Using Amplatzer Septal Occluders

Jozef Masura, MD, PhD, Pavol Gavora, MD, Tomáš Podnar, MD, PhD
Bratislava, Slovakia

OBJECTIVES
The aim of this study was to assess long-term results of percutaneous closure of secundum-type atrial septal defect (ASD II) using Amplatzer septal occluders (ASO).

BACKGROUND
Only immediate-, short-, and intermediate-term results of ASO implantation are known so far. Between September 1995 and January 2000, 151 patients underwent a successful percutaneous closure of ASD II in our institution. All were included in the present study and were followed up until September 2004.

METHODS
RESULTS
This group of patients was followed up from 56 to 108 months (median 78 months). The mean stretched defect diameter was 15.9 ± 4.8 mm. There were no deaths or significant complications during the study. At three years of follow-up, all defects were completely closed and remained closed thereafter.

CONCLUSIONS
Since the first human implantation in September 1995, the Amplatzer septal occluder proved as a safe and effective device for percutaneous closure of ASD II. (J Am Coll Cardiol 2005; 45:505-7) © 2005 by the American College of Cardiology Foundation
Device closure of atrial septal defects with the Amplatzer septal occluder: Safety and outcome in infants
Karim A. Diab, MD, Qi-Ling Cao, MD, Emile A. Bacha, MD, and Ziyad M. Hijazi, MD, MPH

<table>
<thead>
<tr>
<th>Patient no.</th>
<th>Age (mo)</th>
<th>Gender</th>
<th>Weight (kg)</th>
<th>Diagnosis</th>
<th>Qp/Qs</th>
<th>ASD size (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5.6</td>
<td>M</td>
<td>5.6</td>
<td>Down syndrome, secundum ASD, pulmonary hypertension</td>
<td>2.6</td>
<td>7.3</td>
</tr>
<tr>
<td>2</td>
<td>10.9</td>
<td>M</td>
<td>4.0</td>
<td>Secundum ASD, PDA, branch PA stenosis</td>
<td>2.3</td>
<td>10.0</td>
</tr>
<tr>
<td>3</td>
<td>7.8</td>
<td>M</td>
<td>5.8</td>
<td>Alagille syndrome, PPS, PFO</td>
<td>1.3</td>
<td>2.0</td>
</tr>
<tr>
<td>4</td>
<td>11.5</td>
<td>M</td>
<td>8.3</td>
<td>Secundum ASD</td>
<td>2.4</td>
<td>15.0</td>
</tr>
<tr>
<td>5</td>
<td>0.5</td>
<td>M</td>
<td>4.6</td>
<td>Critical AS s/p angioplasty, PDA, secundum ASD</td>
<td>9.0</td>
<td>9.0</td>
</tr>
<tr>
<td>6</td>
<td>7.8</td>
<td>F</td>
<td>6.9</td>
<td>Secundum ASD, AVNRT</td>
<td>1.5</td>
<td>5.0</td>
</tr>
<tr>
<td>7</td>
<td>11.2</td>
<td>F</td>
<td>7.2</td>
<td>Secundum ASD</td>
<td>2.0</td>
<td>12.0</td>
</tr>
<tr>
<td>8</td>
<td>2.2</td>
<td>M</td>
<td>3.8</td>
<td>Coarctation of aorta s/p repair, subvalvular AS, bicuspid AoV, small LV</td>
<td>1.0</td>
<td>4.0</td>
</tr>
<tr>
<td>9</td>
<td>7.9</td>
<td>M</td>
<td>5.1</td>
<td>Secundum ASD</td>
<td>2.7</td>
<td>12.0</td>
</tr>
<tr>
<td>10</td>
<td>11.9</td>
<td>F</td>
<td>7.0</td>
<td>Secundum ASD</td>
<td>2.3</td>
<td>14.8</td>
</tr>
<tr>
<td>11</td>
<td>10.6</td>
<td>F</td>
<td>6.5</td>
<td>Secundum ASD, multiple mVSDs</td>
<td>3.6</td>
<td>10.0</td>
</tr>
<tr>
<td>12</td>
<td>10.1</td>
<td>M</td>
<td>7.5</td>
<td>Down syndrome, secundum ASD</td>
<td>2.3</td>
<td>16.0</td>
</tr>
<tr>
<td>13</td>
<td>2.2</td>
<td>M</td>
<td>3.0</td>
<td>BPD, secundum ASD</td>
<td>7.0</td>
<td>7.0</td>
</tr>
<tr>
<td>14</td>
<td>3.1</td>
<td>F</td>
<td>3.1</td>
<td>BPD, secundum ASD</td>
<td>5.5</td>
<td>5.5</td>
</tr>
<tr>
<td>15</td>
<td>3.4</td>
<td>F</td>
<td>4.0</td>
<td>Secundum ASD, mVSD</td>
<td>8.0, 5.0, 2.0</td>
<td></td>
</tr>
</tbody>
</table>
# Device closure of atrial septal defects with the Amplatzer septal occluder: Safety and outcome in infants

Karim A. Diab, MD, Qi-Ling Cao, MD, Emile A. Bacha, MD, and Ziyad M. Hijazi, MD, MPH

## TABLE 1. Continued

<table>
<thead>
<tr>
<th>Device size (mm)</th>
<th>Additional interventional procedures</th>
<th>Approach</th>
<th>Sheath (F)</th>
<th>FT (min)</th>
<th>PT (min)</th>
<th>Shunt by echo: Immediate/24 h/1 mo/1 y</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.0</td>
<td>None</td>
<td>PC</td>
<td>7</td>
<td>20.5</td>
<td>120.0</td>
<td>C/C</td>
<td>Died</td>
</tr>
<tr>
<td>12.0</td>
<td>PDA coil occlusion</td>
<td>PC</td>
<td>7</td>
<td>18.0</td>
<td>105.0</td>
<td>C/C/C</td>
<td>Bleeding, transfused</td>
</tr>
<tr>
<td>4.0</td>
<td>None</td>
<td>PC</td>
<td>5</td>
<td>10.7</td>
<td>63.0</td>
<td>C/C/C</td>
<td>None</td>
</tr>
<tr>
<td>20.0</td>
<td>None</td>
<td>PC</td>
<td>8</td>
<td>20.6</td>
<td>96.0</td>
<td>C/C/C</td>
<td>None</td>
</tr>
<tr>
<td>11.0</td>
<td>None</td>
<td>PC</td>
<td>7</td>
<td>8.5</td>
<td>68.0</td>
<td>SS/SS/SS/SS/</td>
<td>None</td>
</tr>
<tr>
<td>5.0</td>
<td>EP study</td>
<td>PC</td>
<td>6</td>
<td>17.6</td>
<td>195.0</td>
<td>C/C/C</td>
<td>Arrhythmia, hypotension</td>
</tr>
<tr>
<td>12.0</td>
<td>None</td>
<td>PC</td>
<td>8</td>
<td>5.7</td>
<td>48.0</td>
<td>C/SS/C/C</td>
<td>None</td>
</tr>
<tr>
<td>6.0</td>
<td>Aortic balloon angioplasty</td>
<td>PC</td>
<td>5</td>
<td>22.5</td>
<td>107.0</td>
<td>C/C/C/C</td>
<td>None</td>
</tr>
<tr>
<td>13.0</td>
<td>None</td>
<td>PC</td>
<td>8</td>
<td>36.9</td>
<td>136.0</td>
<td>C/C/C/C</td>
<td>IVC intimal injury</td>
</tr>
<tr>
<td>14.0</td>
<td>None</td>
<td>PC</td>
<td>8</td>
<td>11.0</td>
<td>62.0</td>
<td>C/C/C/C</td>
<td>None</td>
</tr>
<tr>
<td>12.0</td>
<td>4 mVSD device closure</td>
<td>PC</td>
<td>8</td>
<td>56.0</td>
<td>222.0</td>
<td>C/C/C/C</td>
<td>None</td>
</tr>
<tr>
<td>NA</td>
<td>None</td>
<td>PC</td>
<td>8</td>
<td>18.2</td>
<td>102.0</td>
<td>C/C/C/C</td>
<td>Surgical closure, none</td>
</tr>
<tr>
<td>7.0</td>
<td>None</td>
<td>PA</td>
<td>7</td>
<td></td>
<td></td>
<td>C/C/C/C</td>
<td>Intermittent heart block</td>
</tr>
<tr>
<td>6.0</td>
<td>None</td>
<td>PA</td>
<td>7</td>
<td></td>
<td></td>
<td>C/C/C/C</td>
<td>None</td>
</tr>
<tr>
<td>11.0</td>
<td>mVSD device closure</td>
<td>PA</td>
<td>7</td>
<td></td>
<td></td>
<td>C/C/C/C</td>
<td>None</td>
</tr>
</tbody>
</table>

ASD, Atrial septal defect; Qp/Qs, pulmonary/systemic flow ratio; FT, fluoroscopy time; PT, procedure time; PC, percutaneous; C, closed; PDA, patent ductus arteriosus; PA, peratral; PPS, peripheral pulmonary stenosis; AS, aortic stenosis; s/p, status post; SS, small shunt; AVNRT, atrioventricular node re-entrant tachycardia; EP, electrophysiologic; AoV, aortic valve; LV, left ventricle; IVC, inferior vena cava; mVSD, muscular ventricular septal defect; BPD, bronchopulmonary dysplasia.

**Table 3**

Types of Adverse Events Reported to the MAUDE Database Between January 1, 2002 and June 30, 2007

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Percentage of Reported Events for 18,333 (Estimated) Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device embolization</td>
<td>51</td>
</tr>
<tr>
<td>Cardiac perforations</td>
<td>23</td>
</tr>
<tr>
<td>Thromboembolic complications</td>
<td>5</td>
</tr>
<tr>
<td>Residual/recurrent defect</td>
<td>4</td>
</tr>
<tr>
<td>Device infection</td>
<td>2</td>
</tr>
</tbody>
</table>

Reprinted, with permission, from DiBardino et al. (18).

MAUDE = Manufacturer and User Facility Device Experience.
Device Retrieval
Erosion of Amplatzer Septal Occluder
24 hour Holter in 41 patients pre and directly post ASD device closure
90% no change in baseline rhythm
Change in AV conduction in 7%
Non sustained SVT in 23%
Electrocardiographic Changes and Arrhythmias Following Percutaneous Atrial Septal Defect and Patent Foramen Ovale Device Closure

Jonathan N. Johnson, MD, Michelle L. Marquardt, MD, Michael J. Ackerman, MD, PhD, Samuel J. Asivatham, MD, Guy S. Reeder, MD, Allison K. Cabalka, MD, Frank Cetta, MD, and Donald J. Hagler, MD, FSCAI

(>2 months) ECG or Holter. Results: Pre- and post-procedural ECGs were available in 610 patients (305 females, average age 50 ± 18.1 years, range 1-91 years, 384 PFO, 184 ASD, 42 with multiple defects, mean device size 16 mm, range 5-38 mm). We report an incidence of 5.2% (32/610) of arrhythmias in the 4 months following device placement, including 29 patients with atrial tachyarrhythmias (ATs, 22 fibrillation, 7 flutter), 1 with junctional tachycardia, and 2 with heart block. Among other findings, the average P-wave duration was increased on intermediate follow-up as compared to early follow-up (P < 0.001). Development of new-onset 1st degree AV Block after the procedure was associated with an increased risk of ATs post-procedure (P < 0.0001). Conclusion: We report a low risk of clinically significant post-procedure arrhythmias after device placement. Clinically significant heart block occurred in only two patients (0.3%). Changes in several markers of atrial conduction were found, suggesting an effect of device closure on intra-atrial conduction.
1 year f/u in 23 patients after ASD closure (Holter)
Sinus rhythm in 18 and intermittent atrial rhythm in 5 pts
APCs present in 2 (1 pre-existing, 1 new)
1 patient with rare PVCs
Masked Left Ventricular Restriction in Elderly Patients With Atrial Septal Defects: A Contraindication for Closure?

Peter Ewert, MD, Felix Berger, MD, Nicole Nagdyman, MD, Oliver Kretschmar, MD, Sven Dittrich, MD, Hashim Abdul-Khaliq, MD, and Peter E. Lange, PhD

18 patients > 60 years
Significant increase in LA pressure and E/A ratio of mitral valve in 7/18 (39%) patients
Two patients developed congestive cardiac failure after device closure
56 year old female with h/o HTN and a large ASD

Defect dimensions (2d):
- Average ~ 2.5-3cm
- Retroaortic rim 3mm
- All other rims >=6mm
Baseline Hemodynamics

Qp:Qs ~ 4.1:1
ASD ‘Test’ Occlusion
(32mm ASO)
ASD ‘Test’ Occlusion
Case Reports

Closure of a Moderately Large Atrial Septal Defect With a Self-Fabricated Fenestrated Amplatzer Septal Occluder in an 85-Year-Old Patient With Reduced Diastolic Elasticity of the Left Ventricle

Ralf Holzer, MD, Qi-Ling Cao, MD, and Ziyad M. Hijazi, MD
Conclusions

The Amplatzer devices are well established and easy to use.

The procedure is fairly safe, even though some questions remain to be answered relating to erosions.

The procedure is very effective in closing atrial septal defects.

The challenges of this procedure relate to the more difficult defects, relating to size, number of defects, and rim deficiencies.

Pre-procedural imaging (TTE) may NOT always identify these challenges.

If you are not able and equipped to tackle those difficult ASD as well as dealing with potential adverse events, it may be better to not undertake this procedure at all.