Complications of transcatheter Closure of ASD`s

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ASD Closure as an Emergency Procedure

Interventionist worst scenario
Comparison between transcatheter and surgical closure of secundum atrial septal defect in children and adults

Results of a multicenter nonrandomized trial

442 patients  device closure
154 patients  surgical group

The complication rate was 7.2% for the device group and 24.0% for the surgical group (p < 0.001).

Mortality was 0% for both groups.


Amplatzer vs Occlutech Device

Durability of the Device until full endothelialization & lack of ongoing morbidity during follow up.
THE DEVICE

The Occlutech Figulla Occluder (Occlutech GmbH, Jena, Germany) is constructed from 0.082–0.186 mm Nitinol wires, tightly woven into two flat discs with a 9 mm connecting waist (Figure 1). The device gained CE approval in 2006. The Occluder is available in sizes ranging from 6–40 mm, generally in 3 mm increments, except for sizes 6–12 mm that are supplied in 1.5 mm increments and in 4 mm increments in the size range 36–40 mm. The left atrial disc is 12–16 mm larger and the right atrial disc is 8–10 mm larger than the connecting waist. One important feature in this device is the absence of the left atrial disc microscrew, a move that potentially decreases any chance of clot formation on the left atrial disc. The delivery sheath required varies from 9–14 Fr; however, for the smaller sizes (6–12 mm) an 8 Fr sheath can be used safely.

Figulla ASD occluder versus amplatz septal occluder: a comparative study on validation of a novel device for percutaneous closure of atrial septal defects

Between 2005 – 2009
75 pts
FSO 33 pts
ASO 42 pts

Pac et al, J Interv Cardiol. 2009 Dec
Figulla ASD occluder versus amplatz septal occluder: a comparative study on validation of a novel device for percutaneous closure of atrial septal defects

CONCLUSIONS
Both devices are clinically safe and effective in ASD closure. FSO device has similar outcomes when compared to ASO device. Difficulties in selecting the correct device size in larger defects and larger venous sheath requirement need to be evaluated in further studies.

Pac et al, J Interv Cardiol. 2009 Dec

Possible complications

- Device Embolization.
- Arrhythmias / CHB.
- Thrombus formation.
- Air Embolism
- TIA / Stroke
- Erosions / PE / Tamponade / Death
- SBE
- Cobra formation
- Headache / migraine
Device Embolization

- 1.7 – 4 %
- Most retrieved percutaneously
- Appropriate sizing should avoid this complication
- Appropriate evaluation of the device prior to its release is key and requires multiple views.

Device Embolization

Most important it does not obstruct blood flow to the lung or systemic circulation.
No reported mortality.
**Arrhythmias**

- 0.9 – 2.9 %
- Most transient
- SVT
- CHB, rare < 1%
- Oversizing may be incriminated

**Arrhythmias**

Considering the natural history of secundum ASD, even already altered by defect closure, atrial arrythmias are part of the disease process, and an expected findings, hence to differentiate whether the atrial arrhythmias during follow up are related to device placement or are a consequence of the underlying disease is impossible.
Thrombus Formation

- Rare
- Aspirin 2-3 mg/kg 48 hours before
- Heparin I.V (75-100 U/Kg)
- After: Dual antiplatelet therapy
  Clopidogrel & Aspirin 6 months

Cardiac perforation and erosion

The most dreaded complication is cardiac perforation resulting in pericardial effusion, tamponade, hemodynamic collapse, and possible death.
Cardiac perforation and erosion

1 - Delivery related perforations:
   During delivery of the device itself or other equipment used, e.g., guide wires sheaths. Care must be given to avoid LAA. Tip of the sheath must be pulled back into LA prior to deployment LA disk. Occasionally, is needed to align the LA disk parallel to the septum, extreme care should be exercised.

Cardiac perforation and erosion

2 - Erosion of the device itself:
   Through the cardiac walls can lead to frank perforation and pericardial tamponade.
Cardiac Erosion
Amin et al. 2004

The incidence of device erosion in the United States was 0.1%.

The risk of device erosion with ASO is low and complications can be decreased by identifying high-risk patients and following them closely.

Patients with deficient aortic rim and/or superior rim may be at higher risk for device erosion.

Oversized ASO may increase the risk of erosion.

The defect should not be overstretched during balloon sizing.

Patients with small pericardial effusion at 24 hr should have closer follow-up.

89% deficient aortic or superior rim
ASO app. 2 mm > balloon sized diameter
Cardiac Erosion Amin et al. 2004

28 cases worldwide (incidence of 0.1 % in the USA)

Bacterial Endocarditis

- Extremely rare
- Avoid implantation before 1 month with active infection / sepsis
Study of ASD Closure with Occlutech at National Heart Institute 2/09 - 2/10.

Early Complications

> 20-35 Patients

- Age: 2 Y - 58 Y
- Weight: 10 Kg - 90 Kg

National Heart Institute – Ongoing study for comparing Transcatheter closure ASD Versus Surgery costings.

Device Embolization
- 1 pt Immediate Surgery.
- 12 Hours after deployment Surgery
Embolization prior to deployment

- Name: A G
- Age: 22 Y
- Sex: Female
- Weight: 75 Kg
- Main C/O: SOB with effort, rapid regular palpitation at rest.
- Chest X-Ray: Mild Plethoric Lung
- ECG: IRBBB
- TEE: Large secundum ASD, (2.5 X 2.3 cm)
  - Good Superior & Inferior & Aortic Rims > 0.5cm
  - Total interatrial length 4.4 cm
  - Mild MVP
- Estimated PA pressure 35 mm Hg
Embolization within 24 H

- Name: W K
- Age: 40 Y
- Sex: Female
- Weight: 67Kg
- Main C/O: SOB with effort, rapid regular palpitation at rest.
- TEE: Large secundum ASD, (2.8cm)
- Adequate sup. & Inferior rims
- absent AO rim
Study of ASD Closure with Occlutech at National Heart Institute
2/09 - 2/10.
Early Complications

Cardiac Perforation – Guide Wire (LAA) 1pt → Pericardiocentesis.
Case
LAA Perforation – Guide Wire

Case
LAA Perforation – Guide Wire
Case
LAA Perforation – Guide Wire

Avoiding complications
Proper Indications of Transcatheter closure of ASD

1. Symptomatic or hemodynamically significant shunt (Qp/Qs > 1.5) and/or RV volume overload as shown by TTE.

2. Pts. With a small ASD and a history of paradoxical embolism resulting in either a stroke, TIA or peripheral embolism.
Avoiding complications

contraindications

1. Associated APVD.
2. Sinus venosus ASD or Primum ASD.
3. A Deficient rim (<5 mm) from the ASD to SVC or IVC, Rt. Upper or Lower Pulmonary vein, coronary sinus, mitral or tricuspid valve. (A Deficient ant.rim to AO is not a contraindication).
4. Associated other anomalies requiring surgery.
5. PVR > 8 Woods Units.
7. Contraindications to antiplatelet therapy.
a) Four-chamber view showing the defect (arrow), the inferior anterior rim, and the inferior-posterior rim. (b) Classic short axis view at about 35° demonstrating the defect (arrow), the anterior rim, and the posterior rim. (c) Bicaval view at about 120° demonstrating the superior rim and the inferior rim and the defect (arrow). (d) Same view as above with slight rightward rotation to open up the inferior vena cava. (arrow), the entire inferior rim, and the superior rim. (e) Bicaval view with slight posterior rotation of the probe to open up the coronary sinus.

Full List of equipments required for the ASD closure procedure
Take Home Message

Both for erosions, embolisations, size of the device in relation to defect is the main message. Not to oversize too much to avoid erosions but not to undersize it to cause device embolization.

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Thank You