Fermeture percutanée des CIA : matériels disponibles et résultats

Transcatheter closure of ASD : devices and results

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ASD closure

Interest of percutaneous closure

- Up to December 2008
- Surgical closure (SC) vs percutaneous closure (PC)

- Postprocedural complication rate of 31% in SC pts and 6.6% in PC pts
- The adjusted OR for SC vs PC total complications was 5.4 in favour of PC
- Postprocedural major complication rate was 6.8% in SC pts and 1.9% in PC pts
- The adjusted OR for SC vs PC major complications was 3.81 in favour of PC

Butera. EuroIntervention 2011; 7:377
Transcatheter closure of ASD

Nonoperative closure of left-to-right shunts

Efforts to close left-to-right shunts at Ochsner Medical Institutions have been directed toward atrial septal defects (ASD) and patent ductus arteriosus (PDA). PDA’s were constructed in dogs by interposing a segment of jugular vein between the aorta and main pulmonary arteries. Five dogs in which the PDA was closed by a plug device inserted through the femoral vessels were put to death at 6 to 12 months. Histologic sections showed good fibrous ingrowth with endothelial covering on the aorta and pulmonary artery sides. There were no migrations or residual shunts. At cardiac catheterization, 18 patients had ASD’s sized and located as to position in the septum. The sizes ranged from 15 to greater than 30 mm in diameter. The ASD sizes in patients who underwent standardoperative closure were compared to the measurements at catheterization, and the variation was insignificant. In 5 patients, centrally positioned secundum ASD’s were closed with double umbrella devices, 25 to 33 mm in diameter. Anatomic contraindications for umbrella closure included ASD’s greater than 30 mm in diameter, anomalous pulmonary venous connection, common atrium, inferiorly or superiorly located secundum ASD, and sinus venosus ASD. Follow-up studies from 6 to 12 months on 5 patients with umbrella closure have revealed no hemolytic, arrhythmias, thromboembolism, migration, or other undesirable effects.

Noel L. Mills, M.D.,* and Terry D. King, M.D.** (by invitation), New Orleans, La.

Delivery sheath : 23 F (7.2 mm)

Surgery 1974; 75:383
ASD closure: 30 years later ...

King and Mills. Am J Cardiol 2003
ASD occluders

Clamshell, CardioSEAL, and Starflex (NMT)
1997: modern era

* Who ??
1997: modern era

- Kurt Amplatz, new ideas, new concepts
- Nitinol technology (nickel/titanium): superelasticity, shape memory, radioopacity, MRI compatibility, resistance to fatigue and corrosion
Amplatzer Septal Occluder
up to 40 mm

Largest experience in the world
Pubmed ASO Sep 2015 : 2249 references
Closure with the Amplatzer Septal Occluder
ASD closure with the Amplatzer Septal Occluder
* Up to July 2001, 3535 pts
* Median age: 12.1 yr (10 days - 88 yrs), median weight 41 kg (2.4-137 kg)
* 3460 pts received a single ASD, 45 received 2 devices for multiple ASDs
* Median SD: 18 mm (4-44 mm), median size device 18 mm (4-40 mm)
* Immediate success of implantation: 97.4%
* Minor complications: 2.8% of procedures
* Serious complications: 0.3%
* No device related death

Omeish and Hijazi. J Interv Cardiol 2001;14:37
Treatment of isolated secundum atrial septal defect: impact of age and defect morphology in 1013 consecutive patients

- 2 Italian centers, 1013 consecutive pts, 2000-4
- Age: mean 22 yrs (1-80 yrs), 65% ♀
- Selection TTE and/or TOE ± cath
- 83% pts: selection for transcatheter closure
- Devices: Amplatzer Septal Occluder, Cardioseal/Starflex, Helex

Butera. Am Heart J 2008;156:706-12
Echocardiographic evaluation of ASD and rims

Choice / maximal atrial length: Ø max + 14 mm in apical 4C view or TEE

Deficient rim if < 5 mm except for the anterior rim

Centrally located defect: small to medium defects (up to 18 mm); medium to large defects (18-30 mm), and large defects (>30 mm)

Butera. Am Heart J 2008;156:706-12
Centrally located defect: 73.8% 
- no difference between devices up to 18 mm 
- > 18 mm defects: treated only with the ASO 
- Ø ASO > CS/SF > Helex 
- time of fluoroscopy: shorter with the ASO (p = 0.03)

Deficient rim (< 5 mm except the anterior rim): 4.2% 
- no percutaneous closure except for deficient anterior rim

Deficient anterior rim: 17% (3 technical failures including one embolization). Corrected by ASO only

Butera. Am Heart J 2008;156:706-12
Treatment of isolated secundum atrial septal defect: impact of age and defect morphology in 1013 consecutive patients

- Multiple defect: 4.5%
  - Implantation of 1 or 2 devices (mostly 2 devices ≈ 2/3)

- Multi-fenestrated interatrial septum: 2.7%
  - Aneurysm frequent
  - 1 or 2 devices
  - CS/SF employed, but also cribriform Amplatzer or Helex

- Aneurysmal septum ASIA (septum excursion of more than 10 mm): 8.2%
  - Possible closure in 81%

Butera. Am Heart J 2008;156:706-12
Treatment of isolated secundum atrial septal defect: impact of age and defect morphology in 1013 consecutive patients

- Technical failure: 12 cases (1.4 %): device ablation during cath
- Complications: n = 9 (1 %)
  - embolization/malposition: n = 7 => surgery
  - atrial perforation: n = 2 within the first 24 h due to over-dimension => surgery

- Learning curve: complication 2 % in 2000, 1.8 % in 2001, 1.1 % in 2002, 0.5 % in 2003 and 0.6 in 2004 (p = 0.05)

*Butera. Am Heart J 2008;156:706-12*
Transcatheter closure effective in 80%.
- Centrally located defect < 18 mm: large choice of device.
- Centrally located defect > 18 mm => ASO.
- No anterior rim => Amplatzer.
- Multi-fenestrated defect: CS/SF but also Helex, cribriform ASO.
- CIA s: need for 2 devices.

Butera. Am Heart J 2008;156:706-12
The FSO: double disc system similar to the ASO

- A nitinol wire mesh using a unique braiding technique
- The two retention discs are connected to a central 4-mm waist (device size)
- Polyester patches are sewn within both discs and also the waist to facilitate thrombogenicity and increase the occlusion rate
- In comparison to ASO, FSO has a reduced amount of material with no hub on the left disc
- The connecting system has evolved from initially a microscrew – as the ASO - to recently a hub attached to the loader by 2 lateral hooks
- The double disc can be angled some 50 degrees without tension on the system. All these modifications have increased the flexibility of the device
* No difference between FSO and ASO concerning fluoroscopy time, radiation dose, procedure duration and immediate and late full occlusion

Godart. Arch Cardiovasc Dis 2014
Pac. J Interv Cardiol 2009

* Angle modification to body axis during implantation: left disc 10.6° ± 7.5° and right disc 16.3° ± 7.9°

Haas. EuroIntervention 2014
ASD closure - Occlutech

IRFACODE – personal data

* 1315 pts, until December 2013
* Mean age 28.9 ± 21.4 yrs (0.3 – 83 yrs)
* 66.9 % F / 33 % M, centers (11 countries)
* Indications: L-R shunt: 86.6 %; signs of heart failure: 10.2 %; paradoxical embolism: 5.6 %; cyanosis 0.5 %

* Mean size: 20.5 mm
* Large defect ≥ 24mm: 511 pts (26.1 %)
* 47.9 % no aortic rim, 11.9 % more than one defect, aneurysm 21.5 %
ASD closure - Occlutech

IRFACODE – personal data

* Successful procedure: 98%; F-up: 2.7 yrs
* Immediate closure: 78.6%, at discharge 83.1%, and 96.4% and 97.3 at 6 and 12 months
* Small children ≤ 15 kg: 7.1% => technical success 94.7% and closure rate 95.7%

* Embolization: at implantation 15/1315 = 1.1% and during follow-up: 5/1297 = 0.4%
* AV block: 5 at implantation (device retrieved in 4), and 3 during follow-up
* No erosion or death
CeraFlex™ ASD occluder, Lifetech scientific

* Innovative delivery system with 360° flexible rotation
* Nitinol wire frame with titanium nitride oxide coating with no left atrial hub, and covered with PET
* Waist: 6 – 42 mm and delivery sheath: 8-14 F
CeraFlex™ ASD occluder, Lifetech scientific

- 4 centers in Turkey, comparison between Ceraflex and ASO
- 2010 – 2014, 125 pts, Ceraflex (n = 58) and Amplatzer (n = 67)
- No difference in: pt characteristics, SD, device size, fluoroscopy time
- Immediate and F-up complete occlusion rate were 100%
- No embolization, stroke, pericardial effusion

Astarcioglu. Herz 2015;40S:146
* Hyperion™ ASD Occluder (ASDO), Comed
* Double disc
* No hub on the left disk
* Delivery cable modified: double co-axial system
* Waist Ø: 6 mm – 20 mm (1 mm increment); 20-42 mm (2 mm increment)
* Left disc: +10-14 mm than the waist diameter
* Delivery sheath: 8-14 F
* ASDO with hole design
* But no publication on Pubmed
Nit-Occlud R ASD-R, PFM medical

* Double disc
* Made of a single nitinol wire
* Low profile, polyester membrane on the left disc
* Pre-mounted, advanced over a wire placed in pulmonary vein
* Waist Ø: 8 mm – 30 mm (2 mm increment)
* Left disc: + 8-17 mm than the waist diameter
* Delivery sheath: 8-14 F
Nit-Occlud \(^R\) ASD-R, PFM medical

* NOASD-R device
* Oct 2011-Sept 13 : 74 pts (79.5 % F), age : median 17.2 yr (2-74 yr)
* Implantation succeeded in 73 pts (98.6 %)
* At 6 month-f-up : no residual shunt
* At a mean f-up of 11 months : no device embolization, cardiac erosion, endocarditis, wire fracture, thromboembolism, death...

Peirone et al. CCI 2014;84:464
Nitinol frame with polyvinyl alcohol sails
35 pts, 2002-2004, Lausanne, Switzerland
Age: 43 ± 21 yrs, (7 – 77 yrs)
Implantation success: 89% (31/35 pts)
Immediate closure: 80%
Delivery sheath 13 F
At late f-up (17 mos): full occlusion: 96% (30/31)
Complications: air embolism (n = 2)
Caution in very large defect over 20 mm

Goy. CCI 2006;67:265
Occluders from Cardia

<table>
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<tr>
<th>Product Code</th>
<th>Centering Mechanism</th>
<th>Diameter</th>
<th>Delivery Sheath</th>
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**ULTRASEPT** Atrial Septal Defect Closure Device (latest version)

The Gore Septal Occluder (the new Helex device)

Helex is a circular double-disk nitinol wire composed of single flexible nitinol wire frame helically shaped and draped with a thin membrane of e PTFE

- GSO sizes: 15, 20, 25 and 30 mm
- Device choice: SD x by a factor 1.5
- Sheath: 12 F
Jul-Nov 2012, UK multicentre experience, n = 22 pts, ASD < 17 mm

- Successful implantation: 21/22 (1 PA embolisation)
- Acute and 3-month follow-up closure rates were 100% and 100%
- No difference with ASO concerning: results, procedure time and fluoroscopy time

- Decreased erosion potential
- Decreased thrombogenicity due to absence of an exposed nitinol frame on the left side
- Possibility of preserved transseptal access
- Ability of the device to splay around the aorta

Smith. CCI 2014;83
Results of US – FDA clinical trial

- 2003-2006, 137 pts, 13 US centers
- Successful implantation: 100%
- 122 pts with a 12-month follow-up
- 5 major adverse events
  - 2 embolisations
  - 2 wire fractures => removal
  - 1 unrelated death
- Wire frame fractures: 11.7% with no clinical symptoms (↑ with device size)
- 12 months: fully occluded (70.1%); insignificant leak (29.1%) and significant leak (0.9%)
- No erosion, no sudden death
- Instructions: device-size-to defect-size ratios ≥ 2.1 and limitation of use in ASD ≤ 18 mm

Javois. J Am Coll Cardiol Intv 2014
Bioabsorbable atrial septal occluder

- **BioSTAR** (NMT Medical Inc)
- Modification of the STARFlex (Cobalt–based-alloy) with bioabsorbable fabric (porcine intestinal submucosa)
- Device-to-defect ratio ≈ 2, delivery sheath 11 F
- Potential advantages: decreased long-term thrombogenicity, preserved transseptal access, decreased inflammatory response, reduced arrhythmogenicity and erosion potential

- Oct 2009 – Dec 2010, 33 pts, SD ≤18 mm
- 2 failed procedures (deficient aortic rim => ASO) + 1 device embolized in PA (surgery)
- Rate of full occlusion: at 24 h (77 %), 97 % at 15 mos

*Baspinar, Tex Heart Inst J 2012;39:184*
Bioabsorbable atrial septal occluder

- **BioSTAR** (NMT Medical Inc, Boston, Mass) comparison with ASO
- Occlusion of small to moderate atrial defects (SD < 16 mm)
- Acute and 6 month F-up closure rates for Biostar were 90 % and 100 % vs 100 % and 100 % for ASO
- Procedure time longer for Biostar
- Fluoroscopy time longer for Biostar

*Morgan, CCI 2010,76:241*
1998-2004, 28 cases (14 in USA)
89% had deficient aortic rim and/or high ASD
Perforation: 5 involving roof of LA and Ao, 6 roof of RA and Ao, one both atria, 3 cases perforations between Ao and RA (fistula), site unknown in 3, no perforation seen in 3
Pericardial effusion, tamponade, Ao-RA fistula, sudden death

Diagnosis: within 72 hrs 68%, 29% between 5 days and 8 months, and one had pericardial effusion 3 yrs later
Treatment: 21/28 pts had surgery
* 16 device removal and perforation repaired
* 5 perforation repaired but device was not removed
* 7/20: managed medically by pericardiocentesis and/or observation

Amin. CCI 2004;63:496
Erosion

* 25 articles + 79 distinct events
* True incidence unknown, probably 0.1 – 0.3%
* Mainly related to oversizing (up to 8 mm) and anterior deficient rim, but also Marfan disease, undersizing, device repetitive motion (be gentle with the Minnesota wiggle)

* Need for TOE during implantation
* Need for an overnight in-hospital stay with a next day echo appears a to be a reasonable practise

Crawford. CCI 2012;80:157
Erosion - Recommandations

* NOT Oversize TOO MUCH
* Device should not exceed by 0-2 mm the SD
* Prefer to use the stop-flow technique
* Careful follow-up of pts at risk or with small pericardial effusion at 24-hr
* Mandatory 24-hr follow-up in all pts

Amin. CCI 2004;63:496
Crawford. CCI 2012;80:157
Transcatheter ASD closure: not essential

* Premounted device
* Incurved curve of the delivery sheath
* Size of the sheath
Transcatheter ASD closure: the essentials

- Self-expandable
- Self-centering
- Repositionable
- Large availability in size

- High rate of successful implantation
- High rate of full occlusion
- Safety: minimal risks at implantation and during follow-up
Future

* Less material, softer device
* Different configuration
* Bioabsorbable occluder ???
Conclusions

- Transcatheter ASD closure is now a mature technology
- Procedure is safe and results are very good
- ASO has become the « gold standard » device
- Occlutech device seems to achieve the same results
- Need for larger experience and longer follow-up to confirm safety of all the other devices...