Initial Experience with the ATRIASEPT: A New Device for Transcatheter Closure of Secundum Atrial Septal Defect

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ABSTRACT

Background: The ATRIASEPT (Cardia, Eagan, MN) is a low-profile, self-centering, fully retrievable and repositionable, double-umbrella device with a woven Nitinol frame and polyvinyl alcohol foam sails. It can be used for transcatheter closure of moderate-size secundum atrial septal defects (ASD) up to approximately 24 mm in stretched diameter. The diameter of the inner, self-centering ring is designed to closely match the stretched diameter of the ASD and the total arm length is 14 mm longer than the centering ring diameter. Device endothelialization is excellent. The ATRIASEPT contains significantly less metal than the Amplatzer Septal Occluder.

Methods: Device closure using the ATRIASEPT was performed at 6 different institutions using transesophageal echocardiography. Catheterization data were collected prospectively, but patients (pts) were not randomized. In the majority of pts, device size was chosen using balloon stretched diameter ("stop-flow" technique). Sheath size was 10-12 Fr. Follow-up (F/U) echocardiography (transthoracic or transesophageal) was performed at 1, 3, and 6 months.

Results: The ATRIASEPT was used in 39 pts (26 female), 37 with a single secundum ASD and 2 with additional ASDs. Median age was 25.7 yr (range 3-68 yr) and median weight was 45.3 kg (range 13-115 kg). In 37/39 pts, median ASD balloon stretched diameter was 17 mm (range 9-22 mm). Balloon sizing was not done in 2 pts. The median device centering ring diameter:ASD stretched diameter ratio was 1.06 (range 0.86-2) and the median device total arm length:ASD stretched diameter ratio was 1.84 (range 1.62-3.75). Small, < 2 mm residual left-to-right shunts were present in 5/39 patients (13%) immediately after device release. One pt required device retrieval with subsequent placement of a larger device. At a median F/U of 1 month (range 0-6 months), all pts had proper position of the ATRIASEPT, sinus rhythm, and no mitral regurgitation. A 1.5 mm residual shunt was present in 1 pt (3%) at 1 mo F/U. In the smallest pt (13 kg) with a deficient anterior-superior rim, a 12 mm ATRIASEPT initially caused mild mitral regurgitation that resolved at 3 mo follow-up (F/U).

Summary: The ATRIASEPT is a new low-profile, self-centering, right-side retrievable and repositionable device for closure of moderate-size secundum ASD. Initial F/U shows the ATRIASEPT to be safe and effective in both children and adults. Further study of the ATRIASEPT is warranted.

BACKGROUND

DEVICE CHARACTERISTICS

- Easy loading with locking bioptome delivery system
- Low-profile, self-centering, double-umbrella device design
- 6-arm, 19-strand woven Nitinol frame with polyvinyl alcohol (PVA) umbrellas that articulate individually to conform to septal anatomy *before and after* device release
- Centering ring sizes: 12 – 34 mm diameter (2 mm increments)
  - 22 mm diameter device was the largest available in this series
- Total arm length is 14 mm greater than centering ring diameter
- Fully retrievable and repositionable *without* removing the device
- No exposed metal on the left atrial umbrella
- Excellent device endothelialization

OBJECTIVE

- To evaluate the safety and efficacy of the ATRIASEPT device for closure of moderate-size secundum ASD

METHODS

PATIENTS

- Pediatric and adult patients with secundum atrial septal defect – data gathered prospectively

PROCEDURES

- Transesophageal echocardiography
- Balloon stretched diameter obtained using color-flow occlusion technique
- Device size chosen so that centering ring diameter closely matches balloon stretched diameter of defect
- 10 – 13 Fr delivery sheaths
- Follow-up with transthoracic echocardiography at 1, 3, and 6 months

RESULTS

PROCEDURAL

- N = 39 patients; 26 female (67%)
- Median age = 25.7 years (range 3 – 68 years)
- Median weight = 45.3 kg (range 13 – 155 kg)
- Median stretched diameter (37/39 patients) = 17 mm (range 8 – 22)
  - Balloon sizing was not performed in 2 patients
- Median device centering ring:ASD stretched diameter ratio = 1.06 (range 0.86 –2)
- Median total arm length:ASD stretched diameter ratio = 1.86 (range1.62 – 3.75 mm)
- 5/39 (13%) had small, < 2 mm color-flow diameter left-to-right shunts immediately after device release
- 1/39 (3%) patient (13 kg, with deficient anterior-superior rim) developed mild mitral regurgitation immediately after placement of a 12 mm ATRIASEPT
- 1/39 (3%) patient required device retrieval with subsequent placement of a larger device

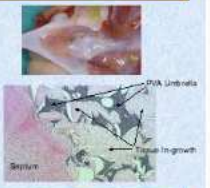
FOLLOW-UP

- Median follow-up 1 month (range 0 – 6 months)
  - Stable device position in 39/39 patients (100%)
  - Sinus rhythm in 39/39 patients (100%)
  - 1/39 (3%) patient had a 1.5 mm left-to-right shunt
  - Mitral regurgitation resolved in the smallest (13 kg) patient

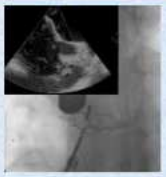
RESULTS

ATRIASEPT left atrial disk (left), centering mechanism (right) and appearance during delivery (bottom)

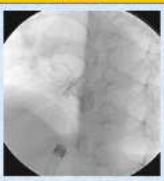
ATRIASEPT endothelialization (top) and microscopic appearance (bottom) at 137 days (limit)



ATRIASEPT attached to delivery cable by TEE (top) and lateral fluoroscopic (bottom)



ATRIASEPT released from delivery cable, lateral fluoroscopy



CONCLUSIONS

- The ATRIASEPT is safe and effective for closure of secundum atrial septal defects up to 22 mm in children and adults (larger devices were *not* available at the time of this series)
- Further study of the ATRIASEPT, including the larger devices up to 34 mm, is warranted