

INITIAL EXPERIENCE WITH THE ATRIASEPT: A New Device For Transcatheter Closure Of Secundum Atrial Septal Defect.

Our thanks to:

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OBJECTIVE:

To evaluate the safety and efficacy of the new ATRIASEPT device.

Patients

7 different international centers
Pediatric and adult patients with secundum ASD
Prospective, non-randomized data collection

N = 58; 36 (62%) female
Median age = 25.7 years (range 3.17–68 yrs)
Median weight = 45 kg (range 13–155 kg)

Immediate Results

6/58 (10%) pts had small < 2 mm (color Doppler) residual left-to-right shunts
1 through an additional, partially covered defect
1/58 (2%) pt developed mild mitral regurgitation
13 kg pt
Deficient anterior-superior rim
1/58 (2%) pt required device retrieval with subsequent placement of a larger device
1/58 (2%) pt developed a small pericardial effusion
Did not require drainage

Procedures TEE or ICE

Balloon stretched diameter by color-flow occlusion (most patients)
Device size chosen to closely match defect diameter
Median defect stretched diameter = 16.6 mm (range 8–26 mm)
Median device centering ring diameter : defect stretched diameter ratio = 1.08 mm (range 0.86–2 mm)
Median device arm length : defect stretched diameter ratio = 1.88 mm (range 1.62–3.75 mm)
Follow-up TTE at 1, 3, 6, and 12 months

Follow-up

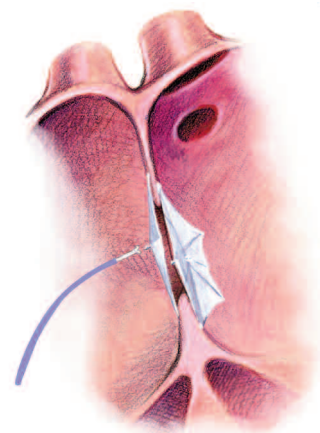
Median F/U = 1 month (range 0–12 mo)
58/58 (100%) pts with stable device position
58/58 (100%) pts with sinus rhythm
2/6 immediate shunts resolved at 1 mo F/U
1/6 immediate shunts persists at 3 mo F/U
Pericardial effusion and mitral regurgitation each resolved at 1 and 3 mos, respectively, in the previously mentioned patients

ATRIASEPT™

Advancing Septal Closure Technology

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 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.



CARDIA®

The ATRIASEPT is safe and effective for closure of moderate-size secundum ASD. Further study of the ATRIASEPT, including the larger device sizes, is warranted.

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