Initial Experience with the Cardia Ultrasept PFO and ASD Occluder

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Background

The circular Ultrasept (Cardia, Eagan, MN, USA) is a low profile, fully retrievable and repositionable septal occluder device. It employs hands-free loading of its stranded Nitinol frame and dual articulating polyvinyl alcohol sails. It is used commonly for transcatheter closure of patent foramen ovale (PFO) and atrial septal defect (ASD).

Methods and Results

Beginning in October 2010, transcatheter closure of patent foramen ovale was undertaken in 6 patients with known right-to-left atrial shunting and presumed paradoxical emboli and in 4 patients with moderate ASD (range before balloon sizing varied from 10 mm to 17 mm) using the Cardia Ultrasept device. (10 patients total)

For PFO closure, 4 patients received a 25 mm device and 2 patients received a smaller 20 mm device. For ASD closure, device sizes varied between 12 mm and 22 mm. Implantations were conducted under local sedation together with TEE guidance. Total procedure duration was in all cases less than 35 minutes with fluoroscopy times of approx 6 minutes. Deployment rate was 100 %. An echocardiogram and chest x-ray showed all devices in a correct position at 24 hour follow up with no residual shunts. No complications were seen during the procedures and all patients were discharged from the hospital the next day. All received a double anti-platelet therapy (6 months ASA – 4 weeks Clopidogrel) and no subacute bacterial endocarditis prophylaxis was given.

No immediate or late complications have occurred in any patient. Total follow up time of this patient cohort is 64 months.