CONCLUSIONS Our study showed that the transcatheter closure of large post tricuspid shunts in pediatric patients with severe PAH was safe, feasible and efficacious alternative to conventional surgery.

CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease

KEYWORDS Congenital heart disease, Device closure, Pediatric cardiology

TCT-30

PREMIUM Trial: Double blind study of percutaneous closure of patent foramen ovale with the AMPLATZER PFO Occluder as a treatment for migraine with or without aura

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BACKGROUND Population studies have identified a correlation between migraine and patent foramen ovale (PFO), and observational studies have reported that PFO closure results in improvement in sham-controlled, double blind study of percutaneous closure of PFO. The PREMIUM Trial was a randomized, controlled trial of percutaneous closure of PFO plus medical therapy (112) versus a sham procedure plus medical therapy (107) or without medical therapy (109). Inclusion criteria for randomization included 6-14 days of migraine per month in patients without aura, who also had a patent foramen ovale (PFO), were randomized to either a sham procedure plus medical therapy (107) or percutaneous closure of the PFO plus medical therapy (123). Inclusion criteria for randomization were limited to patients with first degree atrial flutter, or intolerance) of 3 preventive medications and a significant reduction in the total number of headache days (3.4 vs 2.0 days, p=0.05) in the device group. A subset analysis revealed that subjects for whom the majority of migraine attacks included aura had a particularly significant reduction in headache days (19/39, 49% responder rate vs 9/40, 23% responder rate for PFO closure). Complete remission of migraine occurred in 10.8% (8/74) of the device group and 1.5% (1/68) of controls who had a diagnosis of migraine with aura (p=0.02).

CONCLUSIONS Device closure of PFO can be performed safely, but did not result in a 50% or greater decrease in migraine attack frequency compared with a sham procedure, but there was a significant decrease in the mean number of headache days. Subgroup analysis suggests that individuals with aura occurring during the majority of their attacks may respond more favorably to PFO closure, and that a small but significant percentage of migraine with aura patients may experience complete remission of migraine.

CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease

KEYWORDS Clinical Trial, Migraine, Patent foramen ovale

TCT-31

Title: Immediate and One Year U.S. IDE Trial Results of the New GORE® CARDIOFORM Septal Occluder for Transcatheter Closure of Secundum Atrial Septal Defects

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BACKGROUND The GORE® CARDIOFORM Septal Occluder (studied as GORE® Septal Occluder) was recently FDA approved for the transcatheter treatment of ostium secundum atrial septal defects. It is a low profile double disc device composed of a nitinol 5-wire frame, and covered with expanded polytetrafluoroethylene. We present the first data including both Pivotal and early Continued Access trial subjects with one year follow-up.

METHODS Patients were enrolled from 17 Pivotal and Continued Access U.S. sites in a prospective single arm trial. Follow-up was immediately post-procedure, and at scheduled intervals through one year. Endpoints included successful device placement, immediate and late closure success, and serious adverse events, including serious device-related events requiring reintervention.

RESULTS Between October, 2012 and January, 2014, 125 patients were enrolled with a median age of 7.4 years (range 2.4-78.6). Defects treated had a static diameter of 10.1±3.2mm (maximum 17mm), and stop flow stretched diameter of 12.2±3.2mm (range 5.7-17.5). Deficient retroaortic rim (< 5.0 mm) was present in 36.3%, multiple fenestrations in 18.4%, and atrial septal aneurysm in 10.4%. A CARDIOFORM Septal Occluder was successfully implanted in 92% of patients (115/125), with a serious adverse event rate of 0.8% at one year. Immediate closure success (0.2 mm residual shunt) was 98.9% and a 2.1-4.4 mm residual defect was present in 1.7%. Clinical closure success, defined as normalization of right heart size, was 100%. There were no cases of post-procedural embolization or reintervention.

CONCLUSIONS The GORE® CARDIOFORM Septal Occluder provides a new option for percutaneous closure of small and medium-sized secundum atrial septal defects, with high implant success, occlusion rate, and safety profile.

CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease

KEYWORDS Atrial septal defect, Congenital heart disease, Occluder