Title

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Results of the PREMIUM trial: Patent Foramen Ovale Closure with the AMPLATZER™ PFO Occluder for the Prevention of Migraine

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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 migraine in some patients. The PREMIUM Trial is a randomized, sham-controlled, double blind study of percutaneous closure of PFO with the AMPLATZER™ PFO Occluder (St. Jude Medical, Inc.) as a treatment for migraine with or without aura.

METHODS: 230 subjects with medically intractable migraine with or without aura, who also had a 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 included 6 - 14 days of migraine per month as assessed by a headache specialist, and failure (either lack of efficacy or intolerance) of 3 preventive medications and a significant right to left cardiac shunt determined by a screening Transcranial Doppler (TCD) intravenous agitated saline study. Subjects were randomized on the catheterization table after proof of a PFO was established, to device closure versus a sham control. Subjects and headache specialists were blinded to the randomization allocation. The primary efficacy endpoint was the responder rate percent, defined as a 50% reduction in migraine attacks per month based on the diary during months 10-12 post-randomization. Subjects in the control arm could receive the device after the 1-year blind was over. The primary safety endpoint was the proportion of subjects who experienced a device related serious adverse event through 1 year of follow-up.

RESULTS: There was no difference in the responder rate between the device and the control groups (38% vs 32%, p=0.3). The device was safe: there was 1/202 (0.5%) device related serious adverse event, which was a transient episode of atrial fibrillation. Secondary endpoint analysis showed a statistically significant reduction (p=0.03) in the total number of average HA days in the device group (3.4 days) versus the control group (2.0 days). A subset analysis revealed that subjects for whom the majority of migraine attacks included aura had a significant reduction in HA days (19/39, 49% vs 9/40, 23% responder rate, p=0.015). Complete remission of migraine occurred in 10.8% (8/74) of the device group and 1.5% (1/68) of the control group who had a diagnosis of migraine with aura (p=0.02).

CONCLUSION: Device closure of PFO can be performed safely, but did not result in a 50% or greater decrease in frequency of migraine attacks more commonly than sham therapy in migraine patients. 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.

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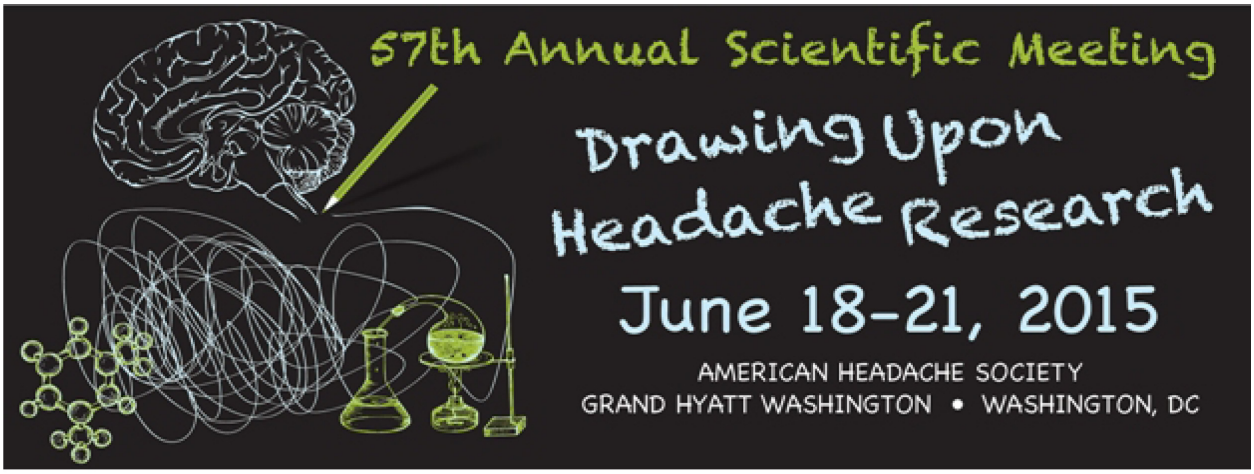

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