Title

Percutaneous Closure of Patent Foramen Ovale in Patients With Migraine - A Patient Level Meta-Analysis of PREMIUM and PRIMA Trials

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Abstract 16148: Percutaneous Closure of Patent Foramen Ovale in Patients With Migraine - A Patient Level Meta-Analysis of PREMIUM and PRIMA Trials

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Abstract

Introduction: Two randomized controlled trials (RCTs), PREMIUM and PRIMA, compared percutaneous closure of a patent foramen ovale (PFO) using the Amplatzer PFO Occluder (Abbott Laboratories, Lake Bluff, Illinois) to medical therapy in reducing monthly migraine days and attacks. Neither trial met its primary efficacy endpoint.

Methods: Individual patient-level data was pooled from PREMIUM and PRIMA to compare the efficacy of PFO closure to medical therapy in reducing monthly migraine days and attacks in a meta-analysis. The mean reduction in migraine days per month, which was PRIMA's primary efficacy endpoint, was computed as the difference between mean migraine days at month 10 - 12 after randomization and mean migraine days at months 1 - 2 prior to randomization. The mean reduction in migraine attacks per month, which was PREMIUM's primary efficacy endpoint, was calculated in a similar manner. All enrolled subjects had to have between 5 and 14 headache days per month and failed at least 2 preventative medications.

Results: The mean reduction of migraine days per month was 1.1 days greater in the PFO closure group compared with the control group (-3.0 vs. -1.9 days, p = 0.03). The mean reduction of migraine attacks per month was 0.6 attacks greater in the PFO closure group compared with the control group (-2.0 vs. -1.4 attacks, p = 0.01).

Conclusions: This meta-analysis of the 2 RCTs that compared the efficacy of percutaneous PFO closure using the Amplatzer PFO Occluder to medical therapy in patients with severe migraines shows that PFO closure is an effective therapy in reducing monthly migraine days and attacks. This suggests that a re-evaluation of PFO closure in preventing severe migraine is warranted.

Footnotes

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