Title

Percutaneous Patent Foramen Ovale Closure for Migraine With the Amplatzer PFO Occluder: A Pooled Analysis of Individual Participant Data From the Randomized Trials

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STRUCTURAL NON-VALVULAR, CONGENITAL HEART DISEASE

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Percutaneous Patent Foramen Ovale Closure for Migraine With the Amplatzer PFO Occluder: A Pooled Analysis of Individual Participant Data From the Randomized Trials

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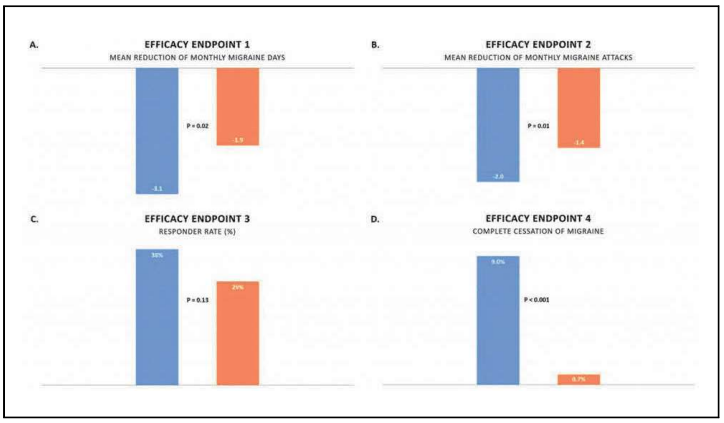
BACKGROUND Two randomized controlled trials, PREMIUM and PRIMA, compared percutaneous closure of patent foramen ovale (PFO) using the Amplatzer PFO Occluder for medical therapy in reducing monthly migraine days and attacks. Neither trial met its primary efficacy endpoint.

METHODS Individual patient-level data from these 2 randomized controlled trials were pooled and analyzed. Efficacy endpoints were mean reduction in monthly migraine days, mean reduction in monthly migraine attacks, responder rate (defined as ≥50% reduction in monthly migraine attacks), and percentage of patients who experienced complete migraine cessation.

RESULTS Among 337 subjects, 176 were randomized to device closure and 161 were randomized to medical therapy only. At 12-month follow-up, 3 of 4 efficacy endpoints were met. The mean reduction of monthly migraine days was 1.2 days greater in the PFO closure group compared with the control group (-3.1 vs. -1.9 days, p = 0.02) (Figure A). The mean reduction of monthly migraine attacks was 0.6 attacks greater in the PFO closure group compared with the control group (-2.0 vs. -1.4, p = 0.01) (Figure B). The responder rate of ≥50% reduction in monthly migraine attacks was not significantly greater in the PFO closure group compared with the control group (38% vs. 29%, p = 0.13) (Figure C). The percentage of patients who experienced complete cessation of migraine was significantly greater in the PFO closure group compared with the control group (9% vs. 0.7%, p < 0.001) (Figure D).



CONCLUSION The results of this patient-level pooled analysis warrant a re-evaluation of PFO closure in treating episodic migraine.

CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease