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Coincidental impact of transcatheter patent foramen ovale closure on migraine with and without aura — A comprehensive meta-analysis

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ABSTRACT

Background: We analyzed the literature to assess the coincidental impact on migraines of transcatheter patent foramen ovale (PFO) closure performed for secondary stroke prevention.
Methods: We searched Medline, EMBASE, and the Cochrane database for studies published up until August 2013. We included English-language studies that provided information on complete resolution or improvement in migraine headaches following PFO closure. Two study authors identified 375 original articles and both independently reviewed 32 relevant manuscripts. Data including study methodology, inclusion criteria, PFO closure and migraine outcomes were extracted manually from all eligible studies. Pooled odds (and probability) of resolution or improvement of migraine headaches were calculated using random-effects models.
Results: Twenty studies were analyzed. Most were uncontrolled studies that included a small number of patients with cryptogenic stroke who had undergone PFO closure and had variable time of follow-up. The probability of complete resolution of migraine with PFO closure (18 studies, 917 patients) was 0.46 (95% confidence interval 0.39, 0.53) and of any improvement in migraine (17 studies, 881 patients) was 0.78 (0.74, 0.82). There was evidence for publication bias in studies reporting on improvement in migraines (Begg's $p = 0.002$), but not for studies on complete resolution of migraine ($p = 0.3$). In patients with aura, the probability of complete resolution of migraine post-PFO closure was 0.54 (0.43, 0.65), and in those without aura, complete resolution occurred in 0.39 (0.29, 0.51).
Conclusions: Among patients with unexplained stroke and migraine undergoing transcatheter PFO closure, resolution of headaches occurred in a majority of patients with aura and for a smaller proportion of patients without aura.
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1. Introduction

Migraine is a primary headache disorder. Twelve percent of the adult U.S. general population have migraines, of which 30% have associated aura [1,2]. A foramen ovale is an embryological inter-atrial shunt that remains patent in up to 25% of the general adult population based on autopsy evaluation [3]. Patent foramen ovale (PFO) has been noted in 40% to 60% of migraineurs [4], especially in those with preceding aura [5–7]. In addition, migraineurs have been known to have intracardiac right-to-left shunting more commonly [5]. A PFO provides the potential for shunting portal and systemic venous metabolites like serotonin to the cerebral blood flow, bypassing their removal during pulmonary circulation passage. Serotonin can lead to platelet activation and aggregation in the cerebral circulation and is thought to be the initiating trigger of migraines in susceptible individuals [8]. Similar to PFO, the creation of an ASD with transseptal puncture for catheter ablation of atrial fibrillation has been suggested to be associated with migraine headaches that resolve over time, presumably as the ASD closes [9].

The results of available studies involving PFO and migraine, and the influence of PFO closure on resolution of migraine symptoms are variable. In a population-based cohort study, PFO detected with transthoracic echocardiography and agitated saline was not associated with self-reported migraine [10]. The MIST trial (Migraine Intervention With STARFlex Technology) was a negative randomized sham-controlled study on PFO closure for drug refractory migraines [11].

Abbreviations: CI, confidence interval; PFO, patent foramen ovale; RCT, randomized controlled trial.

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Table 1
Studies included in the meta-analysis.

No.	Author	Year	Design	Patient subset	Migraine assessment	Follow-up (months)	Antiplatelet drugs
1.	Wilmshurst [26]	2000	Uncontrolled	Decompression illness Paradoxical embolism Large ASD	Questionnaire for frequency, duration, and intensity of migraine episodes	9–30 m	Aspirin 6 m
2.	Morandi [27]	2003	Uncontrolled	Cryptogenic stroke	Questionnaire for frequency, duration, and intensity of migraine episodes	12	Aspirin 6 m
3.	Post [28]	2004	Uncontrolled	Paradoxical embolism Systemic desaturation	Questionnaire for frequency, duration, and intensity of migraine episodes	6	Low dose aspirin (duration not mentioned)
4.	Schwerzmann [29]	2004	Uncontrolled	Paradoxical embolism	Neurologist classified the headache	12	Clopidogrel 1 m Aspirin 6 m
5.	Azarbal [30]	2005	Uncontrolled	Cryptogenic stroke	MIDAS	12	Clopidogrel 3 m Aspirin indefinitely
6.	Mortelmans [18]	2005	Uncontrolled	ASD	Questionnaire for frequency, duration, and intensity of migraine episodes	29	–
7.	Reisman [31]	2005	Uncontrolled	Paradoxical cerebral embolism	Standardized migraine questionnaire	12	Clopidogrel 3 m Aspirin 6 m
8.	Anzola [32]	2006	Case–control	Stroke	MSS	12	Aspirin 300 mg
9.	Giardini [13]	2006	Uncontrolled	Stroke/TIA	MIDAS	12	Aspirin 12 m Ticlopidine 3 m Warfarin 6 m with thrombophilia
10.	Slavin [33]	2007	Uncontrolled	Cryptogenic stroke TIA Desaturation	MIDAS Frequency and severity assessed	30	–
11.	Dubiel [34]	2008	Uncontrolled	Paradoxical embolism	Questionnaire for frequency, duration, and intensity of migraine episodes	38	Aspirin 6 m
12.	Jesurum [35]	2008	Uncontrolled	Paradoxical cerebral embolism	Questionnaire for frequency, duration, and intensity of migraine episodes	24	Clopidogrel 3 m Aspirin ≥6 m
13.	Luermans [36]	2008	Uncontrolled	Paradoxical embolism	Questionnaire for frequency, duration, and intensity of migraine episodes	6	Clopidogrel 1 m Aspirin ≥6 m
14.	Chessa [37]	2009	Uncontrolled	TIA Ischemic lesions on CT/MRI Severe migraine	MSS	6	Aspirin + Clopidogrel 1 m Aspirin 5 m
15.	Kimmelstiel [38]	2009	Case–control	Stroke/paradoxical embolism	MIDAS	3	Clopidogrel 6 m Aspirin indefinitely
16.	Vigna [39]	2009	Case–control	Subclinical brain MRI lesions	Questionnaire for frequency, duration, and intensity of migraine episodes	16	Clopidogrel 3 m Aspirin 6 m
17.	Wahl [40]	2010	Uncontrolled	Paradoxical embolism	Questionnaire for frequency, duration, and intensity of migraine episodes	60	Clopidogrel 1–6 m Aspirin 6 m
18.	Trabattoni [41]	2011	Uncontrolled	Embolic CVA	MSS	28	Aspirin 6 m
19.	Rigatelli [42]	2012	Uncontrolled	High risk for paradoxical embolism	MIDAS	18	–
20.	Nagpal [43]	2013	Uncontrolled	Cryptogenic stroke (93%) Peripheral embolism Hypoxemia Intractable migraine	Frequency and severity on a 0–10 scale	55.2	Aspirin (duration not mentioned) Clopidogrel (duration not mentioned) Warfarin (8%)

ASD, atrial septal defect; CT, computerized tomography; CVA, cerebrovascular accident; MIDAS, migraine disability assessment test; MRI, magnetic resonance imaging; MSS, migraine severity score; TIA, transient ischemic attack.

However, studies in migraineurs with aura have shown a higher prevalence of PFO, and the migraine frequency was reduced with PFO closure as compared to migraineurs without preceding aura [12]. Partial or complete relief of migraine symptoms has been reported with transcatheter PFO closure performed for secondary stroke prevention or prevention of decompression illness [13]. However, most studies have not elucidated the distinction between partial and complete relief from migraines with transcatheter closure of PFO. The difference between migraine with and without aura in patients undergoing PFO device-based closure has not been well defined. The pathogenesis of migraine with aura may differ from that without aura, and this difference may have implications on the effect of PFO closure on migraine outcome.

Given the discrepant results among studies and the limited sample sizes of some of these studies, we performed a meta-analysis to evaluate the effect of PFO closure on resolution or improvement of migraine. Our objective was to conduct a systematic review of relevant existing literature to examine the effect of PFO closure on the migraine symptoms and to identify a subgroup, if any, which could benefit more from PFO closure.

2. Methods

2.1. Search strategy

Following the Meta-analysis of Observational Studies in Epidemiology (MOOSE) guidelines [14], we conducted a comprehensive literature search of studies published in Medline, EMBASE, and the Cochrane Library databases for studies published until August 2013. Keywords used were migraine, migraineurs, migraine headaches, patent foramen ovale or PFO, closure of PFO, heart septal defect, atrial septal defect, atrial septal aneurysm, percutaneous or surgical or operative procedure, transient ischemic attack, stroke, and atrial fibrillation.

Studies that met each of the following criteria were considered eligible for the meta-analysis: 1) published in English, and 2) studies

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