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Editorial Comment

The Conundrum of Migraine Headaches in the Presence of Patent Foramen Ovale

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The accompanying article by the interventional group in Geneva describes their experience in 17 patients who had their PFO closed solely for the indication of severe migraine headaches. This is distinct from most prior observational studies that describe the effect on migraine headache of PFO closure when the procedure was performed primarily to prevent recurrent stroke or decompression illness. Approximately 70% of the patients in this study had a significant decrease or complete abolition (in 24% of cases) of migraine headaches. This current report supplements a recent report by Vigna et al., which describes a positive experience with PFO closure in 53 patients who had migraine headaches and white matter lesions [1]. In that study, the mean number of migraine attacks decreased from 32 to 7 over a 6-month follow up period in the patients who had PFO closure, compared to no significant change in the patients who chose not to have their PFO closed.

The observational data obtained from these recent reports, in conjunction with prior observations in cryptogenic stroke patients, is very consistent. Unfortunately, the only randomized controlled trial to date evaluating the effectiveness of PFO closure for migraine headache treatment, the MIST Trial, did not show significant improvement. However, it is believed that a significant proportion of patients in the MIST Trial had a residual shunt after device insertion, likely due to inadequate closure provided by the Starflex device. In addition, the characteristics of the patient population may be different between those included in the MIST Trial and the observational reports, including the present one from Geneva. I hope neurologists consider all the evidence that is currently available and maintain an open position with respect to the association of migraine headaches and patent foramen ovale.

There are multiple questions that remain concerning PFO closure and migraine. For instance, we still have not identified which characteristics predict the patients likely to respond to PFO closure. Will the responders include only those with visual aura? Approximately 75% of patients with migraine with aura have a significant benefit from PFO closure, but we have seen about 30% of the patients with migraine without aura who also responded to PFO closure [2]. Are the responders more likely to have transient neurologic deficits (which are frequently misdiagnosed as transient ischemic attacks but actually are complex migraine)? Or should we be concentrating on the patient population that already has evidence of brain involvement; that is, those people with white matter lesions on MRI?

Although the majority (60%) of patients screened in the MIST trial had a right to left shunt, there clearly are many people with migraine who do not have a PFO or other etiology of a right to left shunt. In addition, not everyone with a PFO and migraines responds to PFO closure. Nevertheless, as physicians, we are struck by the enormous amount of suffering that patients with frequent migraine must endure. The significant reduction in symptoms, and frequently, the complete abolition of the affliction of migraine is one of the most dramatic effects of percutaneous intervention that I have ever witnessed. The persistence of this benefit over 5–8 years convinces me that this cannot be a placebo affect alone.

This report and other related observational studies can only be used to help generate the hypothesis that right-to-left shunting is physiologically related to induction of migraine headaches. The medical community and the FDA need to design feasible protocols and enroll patients into randomized clinical trials so that we can answer these questions in an appropriate, scientific manner. Two of the randomized clinical trials were stopped because of inadequate patient enrollment due to overly strict inclusion criteria. The PREMIUM

Conflict of interest: Nothing to report.

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Trial by AGA Medical is the only active randomized clinical trial addressing this problem, and is also having difficulty enrolling patients. Hopefully, the protocol can be amended to improve the likelihood of patients meeting the inclusion criteria.

The observational data available at the current time for PFO and migraine is valuable and intriguing. However, it is imperative that neurologists and cardiologists collaborate to formulate an optimal randomized clinical study protocol which will provide the scientific evidence that is needed to validate the effectiveness of PFO closure for the treatment of migraine headaches.

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