

## LETTERS TO THE EDITOR

# Percutaneous Device Closure of Patent Foramen Ovale for Cryptogenic Strokes/Transient Ischemic Attacks

We recently read with interest the recent meta-analysis performed by Agarwal et al. (1) describing transcatheter closure versus medical therapy for patent foramen ovale (PFO) in prevention of recurrent presumed paradoxical embolism. We believe our study (2), which described 1 of the largest series of PFO patients with presumed cryptogenic stroke or transient ischemic attack (TIA) up to that date, meets their inclusion criteria and should have been captured by their MEDLINE search. We reported outcomes in 352 patients with presumed cryptogenic stroke/TIA who underwent device closure of a PFO between December 2001 and June 2006. The mean follow-up duration was 37 months with a maximum follow-up of 6 years (only 7 of 48 studies included in the meta-analysis were followed for this duration or longer). Our subjects underwent rigorous evaluation, including neurologic consultation, brain imaging, thrombophilia screening, and cardiac arrhythmia screens to exclude usual stroke causes before device closure.

The actuarial combined rate for recurrent stroke/TIA was 0.9% at 1 year and 2.8% at 4 years. Thrombophilia and elevated right heart filling pressures were risk factors. There was no association between the presence of residual shunt or atrial septal aneurysm and recurrent events. There was no device thrombus detected in any patient.

After the inconclusive results of the CLOSURE 1 (Safety and Efficacy of the STARFlex Septal Closure System vs. Best Medical Therapy in Patients with a Stroke or TIA due to Presumed Paradoxical Embolism Through a PFO) trial (3), we also await the results of further randomized controlled trials to provide us with evidence-based recommendations to guide our management of patients with PFO and cryptogenic stroke/TIA. Until then, we continue to screen patients meticulously to rule out usual causes of ischemic neurologic events and discuss with them the limitations in our understanding of this common anatomic condition.

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## REFERENCES

1. Agarwal S, Bajaj NS, Kumbhani DJ, Tuzcu EM, Kapadia SR. Meta-analysis of transcatheter closure versus medical therapy for patent foramen

- ovale in prevention of recurrent neurological events after presumed paradoxical embolism. *J Am Coll Cardiol Interv* 2012;5:777–89.
2. Ford MA, Reeder GS, Lennon RJ, et al. Percutaneous device closure of patent foramen ovale in patients with presumed cryptogenic stroke or transient ischemic attack: the Mayo Clinic experience. *J Am Coll Cardiol Interv* 2009;2:404–11.
3. Furlan AJ, Reisman M, Massaro J, et al. Closure or medical therapy for cryptogenic stroke with patent foramen ovale. *N Engl J Med* 2012;366:991–9.

## Reply

We appreciate the interest expressed by Dr. Freund and colleagues in our recent meta-analysis describing transcatheter closure versus medical therapy for patent foramen ovale in prevention of recurrent neurological events attributed to paradoxical thromboembolism (1). We reviewed the study published by the authors in 2009 and agree that this study meets the criteria for inclusion in our meta-analysis and should have been included (2). The conclusions reached by the authors were very similar to those reported in our meta-analysis.

The study in question represents a well-characterized cohort of patients who had a relatively long follow-up. We analyzed our data again after, including this study, and report that there were no significant changes in the results and conclusions reached in our study. The pooled incidence rate of recurrent neurological events was calculated as 0.78%/year as compared with 0.76%/year reported in our original meta-analysis. This difference is not statistically significant. Besides this, the other subgroup analyses reported in our original manuscript, including the impact of residual shunting on recurrent events, remains unchanged.

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## REFERENCES

1. Agarwal S, Bajaj NS, Kumbhani DJ, Tuzcu EM, Kapadia SR. Meta-analysis of transcatheter closure versus medical therapy for patent foramen ovale in prevention of recurrent neurological events after presumed paradoxical embolism. *J Am Coll Cardiol Interv* 2012;5:777–89.
2. Ford MA, Reeder GS, Lennon RJ, et al. Percutaneous device closure of patent foramen ovale in patients with presumed cryptogenic stroke or transient ischemic attack: the Mayo Clinic experience. *J Am Coll Cardiol Interv* 2009;2:404–11.