
Response:

We appreciate the interest in our editorial and the comments by Dr Furlan. We would like to reiterate our initial comment that those involved in the Evaluation of the STARFlex Septal Closure System in Patients with a Stroke and/or Transient Ischemic Attack due to Presumed Paradoxical Embolism through a Patent Foramen Ovale (CLOSURE-I) trial deserve congratulations for shepherding the trial to completion and providing much needed data into an arena that has long been populated with more opinion than fact. We predicted that not many minds would be changed by CLOSURE-I, which failed to prove a benefit from patent foramen ovale (PFO) closure with the StarFlex device. For those who believe that PFO closure must protect patients from recurrent paradoxical embolism, they may interpret the trial as having gone wrong in some of the ways that we outlined. Now that the data from the Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment (RESPECT) and Percutaneous Closure of Patent Foramen Ovale versus Medical Treatment in Patients with Cryptogenic Embolism (PC) trials have been publicly announced, similar analyses are beginning. All 3 trials will contribute greatly to our understanding of the natural history of cryptogenic stroke and PFO in young patients and the impact of different treatment options.

We entirely agree with Dr Furlan that patient selection is crucial both in the context of the clinical trials (to demonstrate efficacy) and in clinical practice (to avoid unnecessary risk from the treatment). The Risk of Paradoxical Embolism (ROPE) study¹ aims to optimize the estimated probability of a PFO-attributable stroke for individual patients and to estimate the risk of a recurrent paradoxical embolism event. This should help to identify patients with the disease in question. Closing PFOs in patients with non-PFO–related stroke mechanisms is unlikely to offer much benefit and so patients must be chosen carefully. As Mark Twain noted, “The difference between the almost right word & the right word is really a large matter—it’s the difference between the lightning bug and the lightning.” In this, then, we agree—to choose the almost right patient for PFO closure would be wrong.

Disclosures

Dr Thaler is on the steering committee for the RESPECT trial (AGA Medical/St Jude). The other author has no conflicts to report.

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Response to Letter Regarding Article, "Critique of Closure or Medical Therapy for Cryptogenic Stroke With Patent Foramen Ovale: The Hole Truth?"
David E. Thaler and Andreas Wahl

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