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Letter to the Editor

Cryptogenic Stroke, Patent Foramen Ovale Closure, and Mid to Long-term Outcomes: Rising Shadows of Doubt

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We read with great interest and appreciation the recently published article by Lee and Kim.[1] We also found many impressive concepts addressed in our recently published review.[2] In light of those topics, we wondered about some challenging issues and blind spots.

The authors[1] mention that recent randomized clinical trials have demonstrated the reduction of patent foramen ovale (PFO)-associated stroke recurrence by PFO closure compared to medical treatment. Including six randomized controlled trials, a recent meta-analysis[3] showed no significant difference in net clinical benefit between PFO closure and medical treatment, emphasizing individualized therapy. Limitations include the cross-sectional nature and a limited number of available randomized controlled trials.[3] Furthermore, most studies have reported results based on relatively short-term follow-up and very low event rates, considering that those subjects will keep the device lifelong, along with the possibility of recurrent stroke from several factors over time, potentially related to the device as well.[2][3] In addition, the low evidence quality has been mentioned, due to the increased risk of imprecisions and biases,[3] while the issues of atrial fibrillation do not seem to be solved either.[2][3] In literature, the results of PFO closure studies/trials can be influenced by many confounding factors due to short/incomplete follow-up,[2-4] including the withdrawal of consent and lost-to-follow-up.[2] A shared multidisciplinary decision-making process is recommended, along with the active documented involvement of the adequately informed patient.[2][4] In our opinion, more extensive, multicentric, long-term studies are lacking and strongly needed, aimed to clearly demonstrate a net clinical benefit, possibly including a number-needed-to-treat calculation, as well as comparing the mid and (mostly) long-term complications, recurrent events, and outcomes in patients with and without a device, including both atrial fibrillation and derived concurrent risk of stroke.[2] About these issues, what is the opinion of the authors?

Notably, where an active program of PFO closure has been approved by a given institution, a potential conflict of interest of the operating team should be considered and excluded during the final patient selection for the procedure. To overcome this issue, a second independent opinion of another (interinstitutional?) team of specialists might be considered.[2] What is the point of view of the authors?

Data Sharing Statement

The data generated in this study is available from the corresponding author upon reasonable request.

Author Contributions

Conceptualization: Dell'Angela L, Nicolosi GL; Data curation: Dell'Angela L, Nicolosi GL; Formal analysis: Dell'Angela L, Nicolosi GL; Investigation: Dell'Angela L, Nicolosi GL; Methodology: Dell'Angela L, Nicolosi GL; Project administration: Dell'Angela L, Nicolosi GL; Resources: Dell'Angela L, Nicolosi GL; Software: Dell'Angela L, Nicolosi GL; Supervision: Dell'Angela L, Nicolosi GL; Validation: Dell'Angela L, Nicolosi GL; Visualization: Dell'Angela L, Nicolosi GL; Writing - original draft: Dell'Angela L, Nicolosi GL; Writing - review & editing: Dell'Angela L, Nicolosi GL.

We congratulate the authors on their valuable article and look forward to hearing their opinions on these matters.

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