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Letter to the Editor: Management of PFO: More evidence, same recommendation

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LETTER TO THE EDITOR:

Management of PFO: More evidence, same recommendation

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I read your article “Closure of patent foramen ovale or medical therapy alone are both appropriate choices for preventing recurrent cryptogenic strokes.”¹ I am writing to inform your readers of additional evidence on this topic.²⁻⁷ A meta-analysis of randomized controlled trials on this topic has recently been published.⁸

Although these studies have the quality marker of being RCTs, they all still have weaknesses. Most notably, they were all open label trials with attrition rates of 20-30%, leading to potential bias in every analysis. This body of literature would significantly benefit from a double-blinded trial; this would be more invasive than a medication-only double-blinded trial, but it can still be done successfully when one intervention is surgical, as Al-Lamee, et al. demonstrated.⁹

The meta-analysis reported a lower risk of stroke with PFO closure, with OR=0.41, [95% CI 0.19, 0.90], NNT of 41. However, the PFO closure was also associated with atrial tachyarrhythmia, OR 4.74 [95% CI 2.33, 9.61], NNT of 25. In general, the overall effect sizes were relatively small, and could be explained by dropout error, which is potentially large.

When interpreting meta-analyses, one has to remember that the results can only be as good as the trials which are included. Since the trials had high dropout rates, this potential error should be considered a weakness of the meta-analysis. The SORT Level of Evidence for this body of literature is B.¹⁰

Patients should be told of both risks of benefits and risks of harm. I agree with Kevin Zhang that both choices are reasonable and require shared decision making between patient and physicians.

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