In patients with a PFO who have had a cryptogenic ischemic stroke or TIA, does percutaneous PFO closure reduce the risk of stroke recurrence compared with medical therapy alone?

Clinical Context

Patients with stroke or TIA should have a careful evaluation to determine the cause and to optimize secondary stroke prevention.15 Because of PFO prevalence in the general population and the high rate of alternative etiologies for recurrent strokes in the prospective studies of PFO, other causes must be excluded before attributing the stroke to the PFO. Judgment regarding any net benefit relative to harm for PFO closure requires a comparison of the magnitudes of effect and the confidence in evidence (summarized in appendix e-8, available as a data supplement to the published article on the Neurology website at Neurology.org). Complicating this comparison is the unknown long-term potential for cumulative increased stroke reduction and late-onset closure device complications. Because of the limitations of the efficacy evidence and the potential for serious adverse events, we judge the risk–benefit tradeoffs of PFO closure by either the STARFlex or AMPLATZER PFO Occluder to be uncertain.

Additional factors influence our recommendations (appendix e-11 clinical contextual profile of the published practice advisory). The STARFlex is not available for routine use in the United States. Some countries have the AMPLATZER PFO Occluder available for clinical use. (At the time of this writing, the AMPLATZER PFO Occluder is undergoing review by the US Food and Drug Administration.)

The costs associated with uncomplicated PFO closure are estimated to be $15,000 or higher.16 Of note, a cost effectiveness analysis concluded that PFO closure may be cost effective in the long term. However, this analysis did not account for the uncertainty in the estimates of closure efficacy. We conclude that the cost effectiveness and closure efficacy remain equally uncertain.17

A final factor influencing the recommendations is anticipated variations in patient preferences because of varying perceptions of risk and ambiguity.18 For example, patients who view having a PFO as a loss (as a “hole in the heart”) may be more likely to seek closure despite the uncertainty of its benefits or known risks, whereas patients who view the potential reduction in stroke risk as a gain are more likely to be averse to the uncertainty of the benefits and associated risks of closure. Informing patients about the commonness of PFO within the general population19 and the difficulty in determining whether their PFOs caused their symptoms will assist patients in selecting an appropriate decision reference frame.20 Matters other than loss-or-gain framing can also influence patients’ benefit–risk preferences and contribute to variations in patient preferences.21
In patients with a PFO who have had a cryptogenic ischemic stroke or TIA, does anticoagulation reduce the risk of stroke recurrence compared with antiplatelet medication?

Clinical Context

Guidelines on secondary stroke prevention also recommend lifelong antithrombotic therapy. Appendix e-8 of the published practice advisory summarizes the risk–benefit tradeoffs associated with the selection of antiplatelet therapy or anticoagulation for preventing recurrent strokes in patients with PFO. This recommendation assumes that there is no other indication (e.g., deep venous thrombosis) for anticoagulation. Because of the uncertainty surrounding the benefit of anticoagulation in the setting of PFO and anticoagulation’s well-known harm profile, we judge that the risk–benefit tradeoff favors the use of antiplatelet medication.

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<td>In the absence of another indication for anticoagulation, clinicians may routinely offer antiplatelet medications instead of anticoagulation to patients with cryptogenic stroke and PFO.</td>
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<tr>
<td>In rare circumstances, such as stroke that recurs while a patient is undergoing antiplatelet therapy, clinicians may offer anticoagulation to patients with cryptogenic stroke and PFO.</td>
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References


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