Top Ten Things To Know
Percutaneous Device Closure of Patent Foramen Ovale for Secondary Stroke Prevention

1. Stroke is the third leading cause of death among adults in the United States and a major contributor to long-term functional impairment and disability.

2. The majority of strokes are ischemic; of these, about 25-40% have no identifiable cause after thorough evaluation and are designated as cryptogenic (CS).

3. A patent foramen ovale (PFO) is a remnant of the fetal circulation and has been identified at autopsy in 27% of patients with normal hearts.

4. Many observational studies suggest a strong association between PFO and CS, but a causal relationship has not been convincingly established for most affected patients.

5. The optimal therapy for prevention of recurrent stroke or transient ischemic attack in patients with CS and PFO has not been defined.

6. Estimates of annual rates of recurrent stroke among patients with PFO range from 1.5-12% and depend on the characteristics of the population studied, including age.

7. No device for PFO closure after cryptogenic stroke has been approved by the FDA.

8. Randomized controlled trials offer the best means for assessing the safety and efficacy of percutaneous device closure relative to anti-thrombotic therapy.

9. Enrollment in ongoing clinical trials has lagged considerably despite frequent calls for participation from the FDA and major professional societies.

10. This advisory is a call to action for all cardiovascular clinicians to consider referral of patients with cryptogenic stroke and PFO to one of these ongoing studies.


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