



Effective Health Care

Patent Foramen Ovale Closure for the Prevention of Stroke Recurrence

Nomination Summary Document

Results of Topic Selection Process & Next Steps

- Patent foramen ovale closure for the prevention of stroke recurrence was found to be addressed by a 2012 systematic review. Given that the existing review covers this nomination, no further activity will be undertaken on this topic.
 - Kitsios GD, Dahabreh IJ, Abu Dabrh AM, et al. Patent foramen ovale closure and medical treatments for secondary stroke prevention: a systematic review of observational and randomized evidence. *Stroke* 2012 Feb;43(2):422-31. PMID: 22180252

Topic Description

Nominator: Organization

Nomination Summary: The nominator questions the role of patent foramen ovale identification and closure in the setting of stroke. The nominator is interested in the comparative effectiveness of percutaneous closure devices compared to surgical and medical treatments.

Staff-Generated PICO

Population(s): Patients with presumed paradoxical embolism (including cryptogenic stroke and transient ischemic attack), asymptomatic patients with incidentally discovered patent foramen ovale; subgroups of interest include the elderly and differences by sex

Intervention(s): Medical management

Comparator(s): Primary surgical treatment, percutaneous closure procedure

Outcome(s): Mortality, rate of recurrent cerebrovascular events (e.g., stroke, transient ischemic attack), potential harms from closure or medical interventions (e.g., vascular injury, cardiac perforation, air embolization, device embolization, early and late thrombosis, atrial arrhythmia, hemorrhage)

Key Questions from Nominator: 1. What is the role of patent foramen ovale identification and closure in the setting of stroke?

Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)

- Topic was found to be addressed by an existing systematic review titled *Patent foramen ovale closure and medical treatments for secondary stroke prevention: a systematic review of observational and randomized evidence*. This review addresses the evidence related to secondary stroke prevention in patients with patent foramen ovale and cryptogenic stroke. The interventions included in this review are percutaneous closure, antiplatelet therapy, and anticoagulants. Fifty-two single-arm studies, seven comparative nonrandomized studies, and pre-publication results from the CLOSURE I trial are included in the review. The review found conflicting results between pooled observational study results and the recent CLOSURE I data, and the authors stated that additional information from ongoing trials is needed before conclusions can be made regarding the use of percutaneous closure devices.

- In 2009, the American Heart Association, American Stroke Association, and American College of Cardiology Foundation issued a call for the completion of randomized clinical trials in this area. The organizations stated that enrollment in trials has lagged despite frequent calls for participation from the FDA and major professional societies, and they strongly reiterated the need for all clinicians involved in the care of patients with cryptogenic stroke and patent foramen ovale to consider referral for enrollment in these landmark trials to expedite their completion and help resolve the uncertainty regarding optimal care for this condition.
 - O'Gara PT, Messe SR, Tuzcu EM, et al. Percutaneous device closure of patent foramen ovale for secondary stroke prevention: a call for completion of randomized clinical trials. A science advisory from the American Heart Association/American Stroke Association and the American College of Cardiology Foundation. *J Am Coll Cardiol* 2009 May 26;53(21):2014-8. PMID: 19460622.

- Based on the calls from professional organizations and the uncertainty in clinical guidelines, it appears that the greatest need in this area is the completion of the ongoing clinical trials. There are currently five ongoing randomized controlled trials of percutaneous closure versus medical treatment with an estimated enrollment of over 3,000 patients.