Percutaneous Closure of Patent Foramen Ovale for Cryptogenic Stroke Prevention

Advisory from the American Heart Association/American Stroke Association and the American College of Cardiology Foundation about a call for completion of randomized clinical trials under development

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Despite the recent advances in stroke diagnosis and treatment, this entity is still the third-leading cause of death among adults in the United States, and a major contributor to long-term functional impairment and disability; approximately one fifth of stroke survivors requiere institutional care for at least 3 months, whereas 15-30% are permanently disabled. (1)

Nevertheless, since out of the 780,000 strokes that occur each year 180,000 are recurrent events, secondary prevention is equally important for survivors of stroke or transient ischemic attack (TIA). (1)

Although the majority of strokes are ischemic, approximately 25% to 40% have no identifiable cause despite a thorough evaluation, and are designated as "cryptogenic stroke" (CS). Since a patent foramen ovale (PFO) has been identified at autopsy in 27% of patients with normal hearts, its presence provides an anatomic substrate for paradoxical embolization as physiopathogenesis of CS, as demonstrated in isolated echocardiographic case reports. (2) Other potential mechanisms of CS among patients with PFO include paroxysmal atrial fibrillation (AF) (which does not necessarily bear any relation to the PFO itself), formation and release of thrombus from the rim of the defect or the left atrial aspect of an associated atrial septal aneurysm.

As far as treatment is concerned, both the AHA/ASA (American heart Association/American Stroke Association) (3) and the ACCP (American College of Chest Physicians) (4) guidelines recommend antiplatelet therapy for patients with ischemic stroke or TIA and PFO (AHA/ASA Class IIa, Level of Evidence B; ACCP grade 1A), unless other indications exist to indicate anticoagulation due to other associated conditions (AF, hypercoagulable state, AHA/ASA Class IIa, Level of Evidence C; ACCP grade 1C). The same AHA/ASA guidelines for secondary stroke prevention state that "insufficient data exist to make a recommendation about PFO closure in patients with a first stroke, although it may be considered for patients with recurrent CS despite optimal medical therapy (Class IIb, Level of Evidence C)." (3)

In this regard, the *Revista Argentina de Cardiología* (Argentine Journal of Cardiology), in its issue 3, has published an interesting controversy about PFO percutaneous closure indication for patients with CS, (5) in which there is agreement on the need to wait for the outcomes of randomized trials currently under development to arrive at final conclusions.

Finally, a commission of the AHA/ASA and the ACC Foundation have also recently highlighted the need to complete the clinical trials under development to obtain the evidences to recommend percutaneous and pharmacological therapies. (6) This commission emphatically encouraged and advised the clinicians involved in the care of patients with CS and PFO (cardiologists, neurologists, internists, radiologists, and surgeons) about the inclusion of patients in the clinical trials currently in progress, in order to facilitate their completion and obtain the outcomes and conclusions that will help solve the uncertainties regarding the optimal treatment for this condition.

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