Reducing recurrent stroke in cryptogenic stroke patients

Patent foramen ovale (PFO) closure patient selection educational guide

Step 1: Tissue diagnosis

Stroke-like symptoms in a patient
Is the MRI positive for acute ischemic stroke?

- **YES** → Acute ischemic stroke
- **NO** → Medical management

Are there signs of advanced atherosclerosis on FLAIR Imaging?
Note: Isolated acute infarcts without chronic associated ischemia are potentially from emboli

- **YES** → Medical management
- **NO** → **Step 2: Vessel imaging**

Step 2: Vessel imaging

Vessel imaging (CTA, MRA, carotid ultrasound)
Is there large vessel atherosclerosis?

- **YES** → Treat as appropriate
- **NO** → Is there other vessel disease? Dissection, RCVS, Moyamoya, Microangiopathic disease, Vasculitis
  - **YES** → Treat as appropriate
  - **NO** → **Step 3: Emboli workup**

Step 3: Emboli workup

Is there any major medical disease in the patient pre-disposing them to thrombosis?
E.g. Cancer, DVT / PE history, autoimmune disease, or 1st degree relative with DVT / PE

- **YES** — Complete both the hematology and shunt workup
  - **Hematologist evaluation**: Hematology workup including venous Doppler for DVT and CT of chest for PE → Is there DVT or PE present?
    - **YES** → Medical management; anticoagulant*
    - **NO** → No anticoagulant required
  - **Shunt evaluation**: Evaluate for paradoxical embolism PFO testing: TCD, TTE, or TEE bubble study → Is a PFO present?
    - **YES** → **Refer for PFO closure and medical management****
    - **NO** → Medical management; consider repeat testing over time if symptoms reoccur
- **NO** → **Cardiac evaluation**: Evaluate for cardiac abnormalities. Is there any cardiac disease including valves, cardiomyopathy, atrial disease, or is there occult atrial fibrillation?
  - **YES** → Conduct prolonged cardiac rhythm monitoring → Is AFIB detected?
    - **YES** → Medical management
    - **NO** → Shunt evaluation

Duration of anticoagulant use varies by case, and the decision to maintain its use in conjunction with PFO closure should be at the physician's discretion.

AFIB	Atrial fibrillation
CT	Computed tomography
CTA	Computed tomography angiography
DVT	Deep vein thrombosis
FLAIR	Fluid-attenuated inversion recovery
MRA	Magnetic resonance angiography
MRI	Magnetic resonance imaging
PE	Pulmonary embolism
RCVS	Reversible cerebral vasoconstriction syndrome
TCD	Transcranial doppler
TEE	Transesophageal echocardiography
TTE	Transthoracic echocardiogram

Used with permission from John J. Volpi, MD, BA Neurology Houston Methodist Hospital. This algorithm represents Dr. Volpi's general clinical practice.

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* The Gore REDUCE Clinical Study did not include patients on anticoagulants. The REDUCE study determined safety and efficacy of patent foramen ovale (PFO) closure with the GORE® CARDIOFORM® Septal Occluder or GORE® HELEX® Septal Occluder plus antiplatelet medical management compared to antiplatelet medical management alone in patients with a PFO and history of cryptogenic stroke. All PFO anatomies were incorporated into this study within indicated sizing parameters of the *Instructions for Use*.

** Refer to *Instructions for Use*.

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INDICATIONS FOR USE in the U.S.: The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of the following defects of the atrial septum: ostium secundum atrial septal defects (ASDs); patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke. **CONTRAINDICATIONS:** The GORE® CARDIOFORM Septal Occluder is contraindicated for use in patients: unable to take antiplatelet or anticoagulant medications such as aspirin, heparin, or warfarin; with anatomy where the GORE® CARDIOFORM Septal Occluder size or position would interfere with other intracardiac or intravascular structures, such as cardiac valves or pulmonary veins; with active endocarditis, or other infections producing bacteremia, or patients with known sepsis within one month of planned implantation, or any other infection that cannot be treated successfully prior to device placement; with known intracardiac thrombi. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and adverse events. ℞ Only

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