

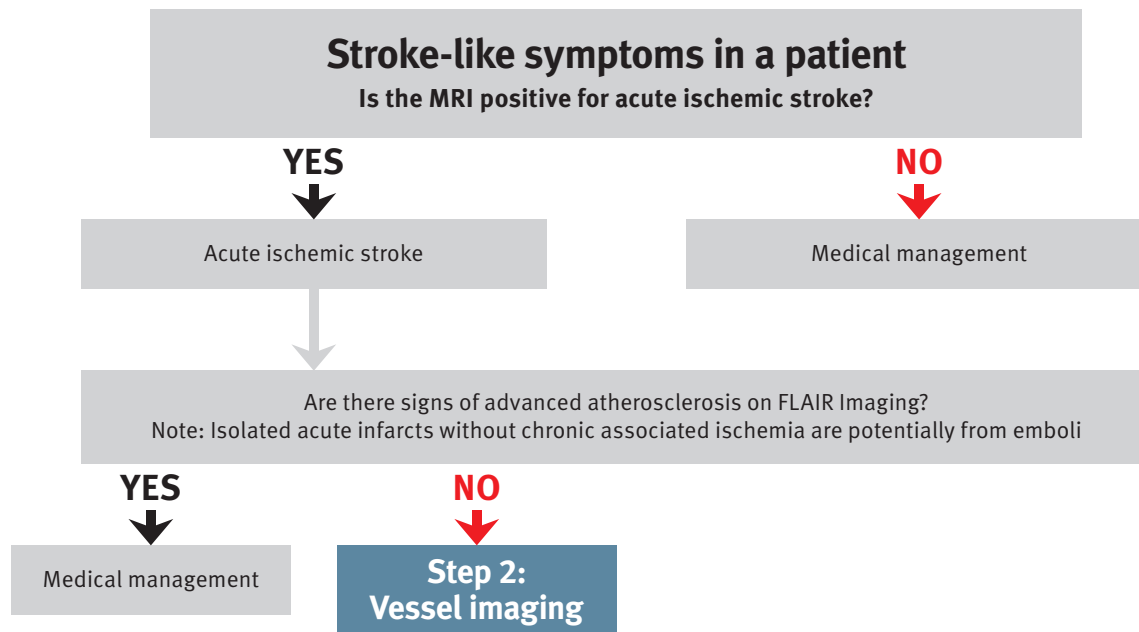
Reducing recurrent stroke in cryptogenic stroke patients

**Patent foramen ovale (PFO) closure
patient selection educational guide**

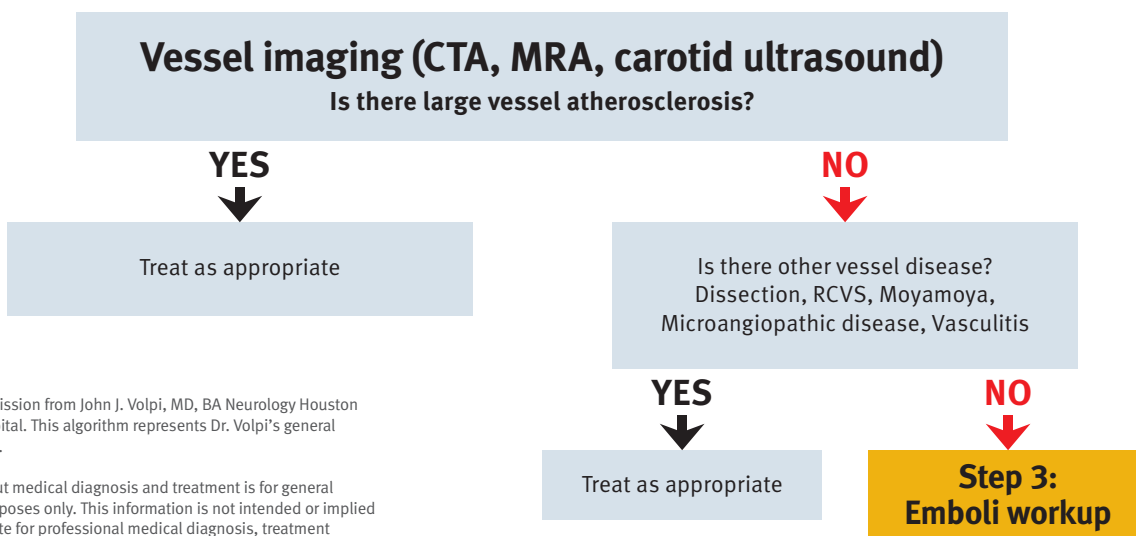
Patient selection algorithm

The following algorithm can help identify patients most likely to benefit from PFO closure.

Step 1: Tissue diagnosis



Step 2: Vessel imaging



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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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

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.

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

NO

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



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
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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*.

INDICATIONS FOR USE outside of the U.S.: The GORE® CARDIOFORM Septal Occluder is a permanently implanted device indicated for the percutaneous, transcatheter closure of atrial septal defects (ASDs), such as ostium secundum and patent foramen ovale.

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. 

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