Reducing recurrent stroke in cryptogenic stroke patients

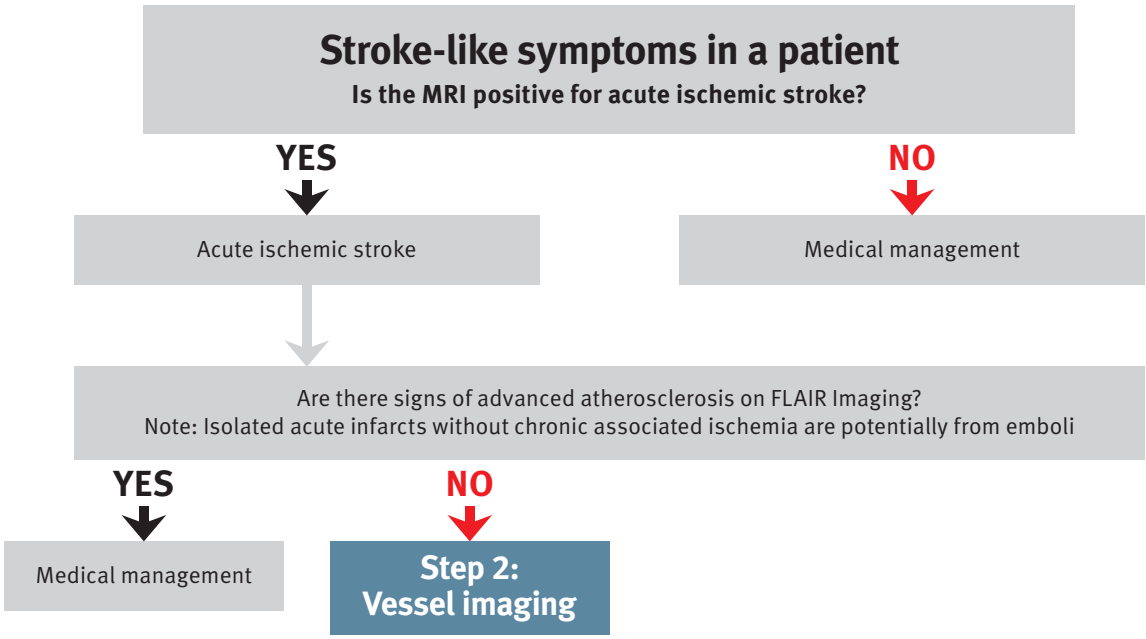
Patent foramen ovale (PFO) closure patient selection educational guide

A HEALTHCARE PROFESSIONAL RESOURCE

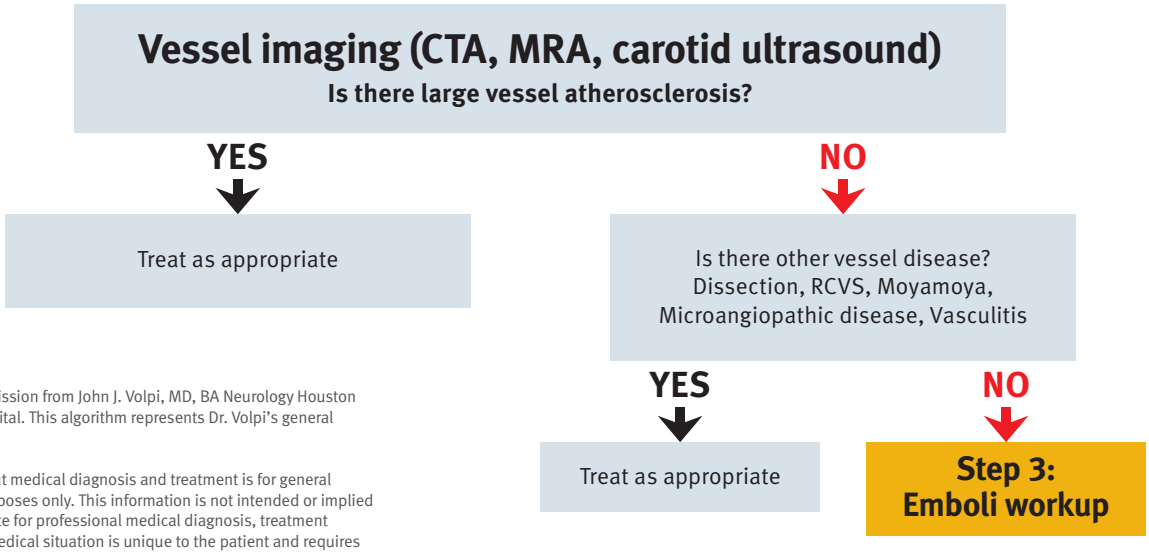
Patient selection algorithm

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

Step 1: Tissue diagnosis

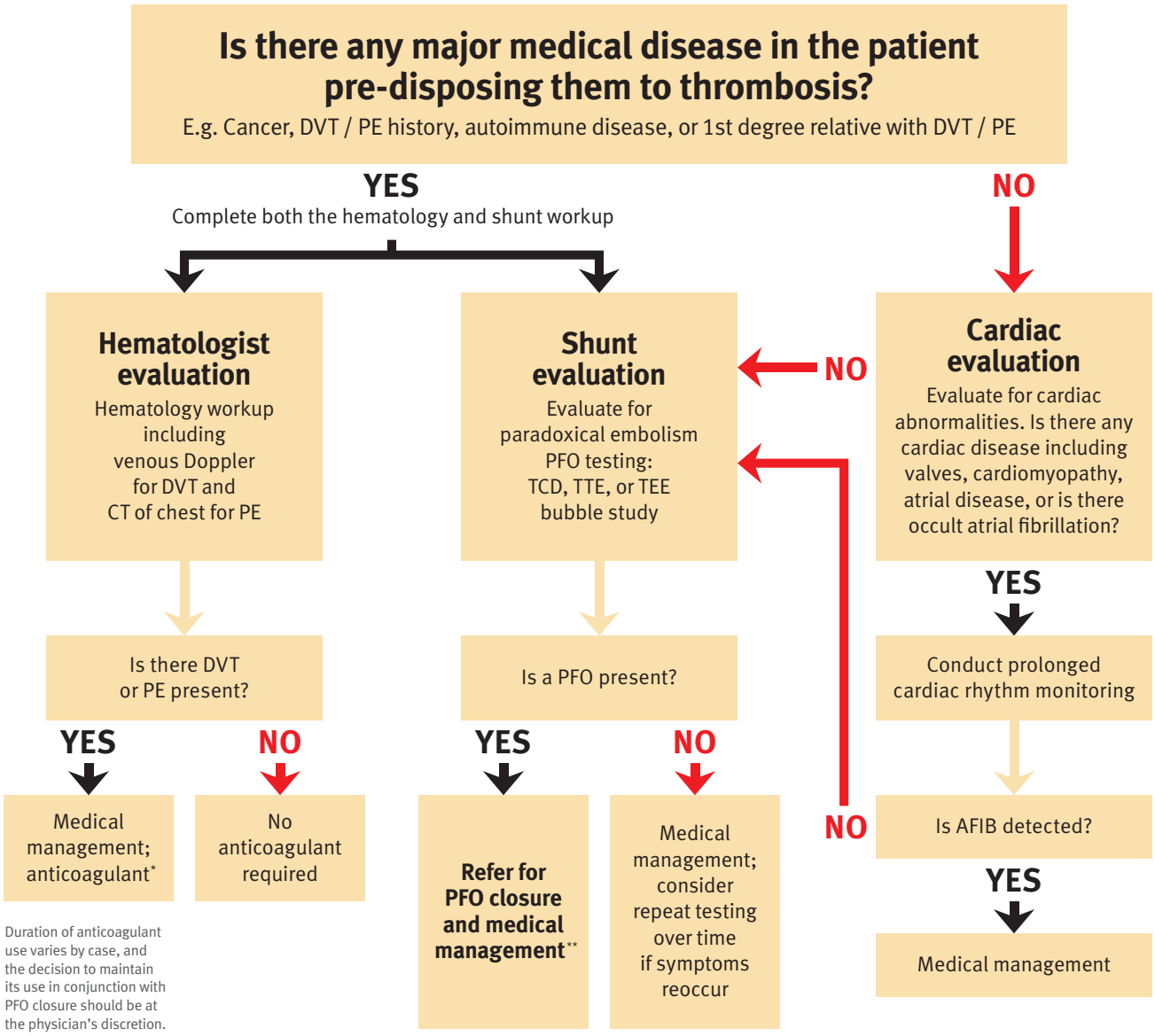


Step 2: Vessel imaging



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

Step 3: Emboli workup



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

W. L. Gore & Associates, Inc.
Flagstaff, AZ 86004

+65.67332882 (Asia Pacific)
00800.6334.4673 (Europe)
800.437.8181 (United States)
928.779.2771 (United States)

goremedical.com

* 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. ℞ Only

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