

Operator and Institutional Requirements for PFO Closure for Secondary Prevention of Paradoxical Embolic Stroke

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Disclosure Statement of Financial Interest

I, **[Zahid Amin]**, DO NOT have a financial interest, arrangement, or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

SCAI expert consensus statement on operator and institutional requirements for PFO closure for secondary prevention of paradoxical embolic stroke

The American Academy of Neurology affirms the value of this statement as an educational tool for neurologists.

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Letter to the editor: NEJM

- When the Early Breast Cancer Trialists' Collaborative Group⁴ performed the first meta-analysis of the value of adjuvant tamoxifen — one of the most effective medications in our pharmacopoeia — for breast cancer, only 6 of 42 randomized trials had shown significant benefit. Only trials with many patients and many events are likely to overcome the play of chance.
- The proper conclusion of these studies, even though they were well designed and carefully performed, is that too few events were observed to draw any conclusion

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PFO Closure

- **Two Approved Devices**
 - Relatively simple procedure
 - Low complication rate in all published trials
- **The procedure continues to spread into wider public domain**
 - Need to ensure that procedure remains safe and efficacious
- **Training of new interventionalists needs to be in a controlled and systematic fashion**

PFO Closure Program

- **Interventionalists should have specific technical and cognitive skillset to master PFO closure**
- **Needs to include all major stakeholders**
 - **Neurologists**
 - **Cardiologists**
 - **Imaging Specialists**
 - **Hematologists**
 - **Anesthesiologist availability**
 - **Cardiac Surgeon availability**

Physicians knowledge base

1. Etiologies of ischemic stroke.
2. Clinical syndromes that mimic stroke.
3. Stroke phenotype classification systems such as ASCOD.¹⁷
4. Stroke risk scoring systems including (CHA2DS2-VASC) and risk of paradoxical embolus (RoPE) scores.^{18,19}
5. Interpretation of invasive and noninvasive stroke neuroimaging results.
6. RCTs comparing PFO closure to medical therapy.
7. Medical therapies for prevention of recurrent stroke including anti-platelet and anti-coagulants
8. Diagnostic evaluation of patients with ischemic stroke
9. Cardiac imaging techniques in patients with ischemic stroke potentially related to a cardiac source of embolism including transthoracic, transesophageal, intracardiac, and contrast echo-cardiography and transcranial Doppler (TCD).²⁰
10. Indications and contraindications for PFO closure.
11. Knowledge and understanding of shared decision making and working in the context of a MDT.²¹

Interventionalists must be familiar with

- Use of Imaging modalities such as TEE and/or ICE
- Expertise in cardiac catheterization procedure, wires, etc.
- Vascular access management
- Use and familiarity with retrieval devices
- Ability to recognize and treat complications

Desirable Experience

- ASD closure
- LAA occlusion
- TSP
 - LVAD when involving TSP
- Mitral paravalvular leak closure
- Balloon mitral valvuloplasty
- Pulmonary vein intervention
- Balloon atrial septostomy

Imaging modalities

- **Fluoroscopy**
 - Wire position (LUPV vs Left atrial appendage)
- **Angiography**
 - Type of PFO: tunnel, limbus thickness, diameter
- **TEE/ICE**
 - Recognition of rims
- **Atrial septal anatomy**
 - Limbus/rims, septum primum, etc

Pre-procedural imaging

- Initial diagnosis establishment
- Characteristic of PFO
- Rule out other causes of paradoxical embolism

TEE/ICE

- Know standard views for atrial septum interrogation
- TEE; 4-chamber view, bi-caval view, aortic short-axis views
- ICE: Caval and short axis view, ways to evaluate AV valve rim
- Exclude Left atrial appendage thrombus

Operator Specific Requirement

- Really, no concrete data available
- Published survey data suggesting 7-50 cases for basic proficiency
- SCAI: >50 life-time congenital or structural catheter based interventions which includes a minimum of 25 procedures involving atrial septum

Procedural specialist

Initial qualification

- Clinical knowledge-base that includes a comprehensive understanding of stroke-related PFO closure and appropriate treatment strategies for this unique patient population.
- Suitable training on the PFO closure device(s) approved by the FDA.
- Understanding of atrial anatomy and imaging
- >50 life-time structural/congenital^b catheter interventions with either a minimum of 25 involving septal interventions^c or 12 specific to PFO device placement.
- Experience with catheter-based management of potential complications, including pericardiocentesis, recognition of device malposition, and embolized device retrieval.

Novice operators

- Mandatory peer-to-peer training course.
- Physician proctor or mentor during interventional training-- 10 cases total.
- Physician proctor present for 3-5 cases for each new device system.

Ongoing

- Over a 2-year period, >30 procedures that involve septal interventions^c or >15 specific to PFO device placement.
- Process for identifying whether additional training is required on the basis of technological or clinical changes.

Medical Facility

- >100 structural/congenital^P catheter interventions in the 2 years leading to PFO program initiation.
- Yearly and thereafter, 50 structural/congenital^P interventions, at least 25 of which involved septal interventions^C and/or 12 specific to PFO device placement.
- Continuous intraprocedure availability of a physician (interventional cardiologist, imaging cardiologist, or cardiac anesthesiologist certified in echocardiography and with experience in guiding structural/congenital heart interventions) with experience at transesophageal echocardiography or intracardiac echocardiography in structural/congenital heart disease.
- Multidisciplinary team that includes necessary staff and expertise for preoperative evaluation, performing the PFO closure procedure, and acute and long-term postprocedure follow-up
- Ready access to an active cardiothoracic surgery program with cardiac surgeons and perfusionists.
- Cardiac catheterization laboratory, or hybrid room with hemodynamic monitoring and high-resolution imaging.

Data Collection and Quality

- Internal collection of all data/assessment/quality improvement
 - Include up to 30 day outcome
- Submission of cases to national or multi-center registry for benchmarking
- Institutional multi-stake-holder process for evaluation of patient selections, outcomes, and quality of care

Proposed quality assessment measures

Metric	Target performance
Operator and institutional requirements met	100%
Percentage of patients who were seen by both a cardiologist and neurologist prior to PFO closure	100%
Procedure-related major adverse outcomes: <ul style="list-style-type: none"> • Mortality • Intraprocedure stroke • Air embolism • Device embolization • Major vascular complications • Major bleeding complications • Atrial fibrillation, transient or sustained, if treatment required, and if oral anticoagulation initiated • Myocardial infarction • Pericardial effusion with and without tamponade • Emergency surgery 	<1% or below the 10th percentile if registry benchmarking data becomes available <5%
Postprocedure major adverse outcome <ul style="list-style-type: none"> • Stroke • Mortality • Deep vein thrombosis or pulmonary embolism if occurring within 6 months of the procedure • Atrial fibrillation, atrial flutter, ventricular tachyarrhythmias, or complete heart block requiring pharmacologic therapy or cardioversion • Thrombus on device detected • Pericardial effusion with and without tamponade • Device erosion • Device explantation • Residual moderate or severe shunting if persistent after 6–12 months 	<1% or below the 10th percentile if registry benchmarking data becomes available
Discharge with dual antiplatelet therapy or anticoagulant and aspirin <ul style="list-style-type: none"> • Provide rationale for deviation in individual patients 	100%
Freedom from recurrent ischemic stroke at 1 year	100%

Conclusion

- PFO are common defects
- We need to ensure that we close PFO only when they meet the appropriate criteria
- We need to keep the complication rate to a minimum
- Physicians planning to perform the procedure must meet and qualify some requirements to close the defect effectively and safely by keeping the complication rate to a minimum