

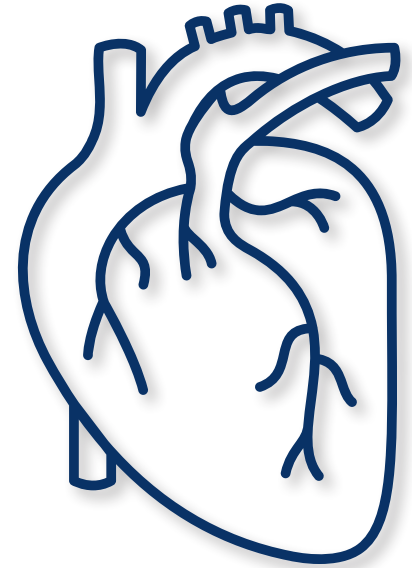
SCAI GUIDELINES FOR THE  
**Management  
of Patent  
Foramen Ovale**  
**KEY TAKEAWAYS**



# Summary of Recommendations

## BACKGROUND

Patent foramen ovale (PFO) is common, present in around 25% of adults. It occurs when a small opening between the right and left atria, known as the foramen ovale, does not close normally as pulmonary resistance and blood pressure decrease in the right side of the heart after birth. PFO may cause symptoms by allowing clots from the venous system to pass into the arterial system and embolize to the cerebral vasculature, or even more rarely into the coronary, visceral, or peripheral arteries. The most well-established complication of PFO is stroke, defined as an ischemic stroke with cortical, large white matter, or retinal infarct in the presence of a PFO and no other identified likely cause. PFO has also been associated with other adverse neurological and embolic events. PFO may be treated with blood thinning medication, or with a percutaneous procedure to close the PFO. Clinicians and patients may be uncertain about the best management option because of limited guidance available for certain clinical scenarios.



## METHODS

These SCAI guidelines are based on original systematic reviews of evidence conducted with support from the Evidence Foundation. The panel followed best practices for guideline development described by the Institute of Medicine and the Guidelines International Network (GIN)<sup>1-3</sup>. The panel used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology to assess the certainty in the evidence and formulate recommendations<sup>4,5</sup>.

## Interpretation of strong and conditional recommendations

The strength of a recommendation is expressed as either strong (“the guideline panel recommends...”), or conditional (“the guideline panel suggests...”) and has the following interpretation:

### STRONG RECOMMENDATION

- **For patients:** most individuals in this situation would want the recommended course of action, and only a small proportion would not.
- **For clinicians:** most individuals should receive the intervention or test. Formal decision aids are not likely to be needed to help individual patients make decisions consistent with their values and preferences.
- **For policy makers:** the recommendation can be adopted as policy in most situations. Adherence to this recommendation according to the guideline could be used as a quality criterion or performance indicator.

### CONDITIONAL RECOMMENDATION

- **For patients:** the majority of individuals in this situation would want the suggested course of action, but many would not.
- **For clinicians:** recognize that different choices will be appropriate for individual patients and that you must help each patient arrive at a management decision consistent with his or her values and preferences. Decision aids may be useful in helping individuals to make decisions consistent with their values and preferences.
- **For policy makers:** policymaking will require substantial debate and involvement of various stakeholders. Performance measures about the suggested course of action should focus on documentation of an appropriate decision-making process.



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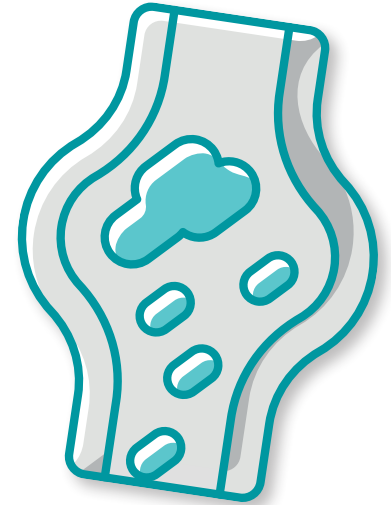
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# 1 Recommendations for Adults without a prior PFO-associated stroke



- 1.1.** In persons experiencing migraines without a prior PFO-associated stroke, the SCAI guideline panel suggests against the routine use of PFO closure for the treatment of migraine (conditional recommendation, moderate certainty of evidence).
- REMARK:** Patients, particularly those with debilitating migraines who have failed to benefit from conventional medical therapy, who place a high value on the uncertain benefits of having their PFO closed and a lower value on the uncertain harms, may reasonably choose PFO closure.
- 1.2.** In self-contained underwater breathing apparatus (SCUBA) divers with prior decompression illness (DCI) and without a prior PFO-associated stroke, the SCAI guideline panel suggests against the routine use of PFO closure to prevent DCI (conditional recommendation, very low certainty of evidence).
- REMARK:** Patients who place a high value on the potential, but uncertain, benefits of having their PFO closed and a lower value on risks may reasonably choose PFO closure.
- 1.3.** In persons with platypnea-orthodeoxia syndrome (POS) and without a prior PFO-associated stroke, in whom other causes of hypoxia have been excluded, the SCAI guideline panel suggests PFO closure rather than no PFO closure (conditional recommendation, very low certainty of evidence).
- REMARK:** Patients who place a higher value on the risks of closure and a lower value on the uncertain benefits may reasonably decline PFO closure.
- 1.4.** In persons with thrombophilia and without a prior PFO-associated stroke, the SCAI guideline panel suggests against the use of PFO closure in addition to antithrombotic therapy (conditional recommendation, very low certainty of evidence).
- 1.5.** In persons with atrial septal aneurysm (ASA) and without a prior PFO-associated stroke, the SCAI guideline panel suggests against the use of PFO closure (conditional recommendation, very low certainty of evidence).
- 1.6.** In persons with systemic embolism and without a prior PFO-associated stroke, in whom other embolic etiologies have been excluded, the SCAI guideline panel suggests PFO closure rather than medical therapy alone (conditional recommendation, very low certainty of evidence).
- REMARK:** Patients who place a high value on the risks and a lower value on the uncertain benefits may reasonably decline PFO closure.
- 1.7.** In persons with a history of transient ischemic attack (TIA) and without a prior PFO-associated stroke, the SCAI guideline panel suggests against PFO closure (conditional recommendation, very low certainty of evidence).
- REMARK:** Patients, particularly those with recurrent, high-probability TIAs, who place a high value on the uncertain benefits and a low value on procedural risks may reasonably choose PFO closure.
- 1.8.** In persons with a history of deep vein thrombosis (DVT) and without a prior PFO-associated stroke, the SCAI guideline panel suggests against PFO closure (conditional recommendation, very low certainty of evidence).

## 2 Recommendations for adults with a prior PFO-associated stroke: percutaneous PFO closure versus antiplatelet therapy



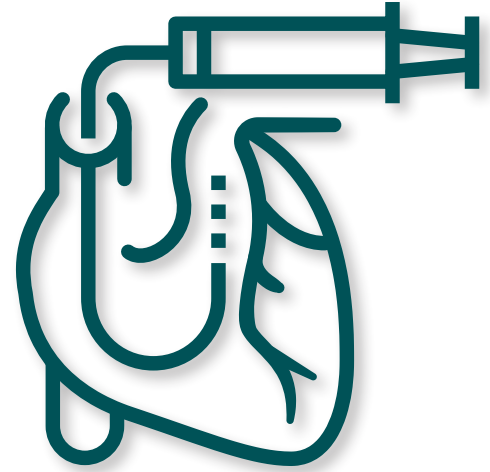
- 2.1.** In patients between the ages of 18 and 60 with a prior PFO-associated stroke, the SCAI guideline panel recommends PFO closure rather than antiplatelet therapy alone (strong recommendation, moderate certainty of evidence).
- REMARK:** This recommendation is independent of patient anatomy (i.e., presence of ASA, size of shunt) due to limited clinical data on these sub-populations. A RoPE (risk of paradoxical embolism) score  $\geq 7$  may identify patients who are likely to receive greater benefit from PFO closure.
- 2.2.** In patients 60 years or older with a prior PFO-associated stroke, the SCAI guideline panel suggests PFO closure rather than long-term antiplatelet therapy alone (conditional recommendation, very low certainty of evidence).
- REMARK:** Patients in this age group who place a lower value on the uncertain benefits of PFO closure and a higher value on the possible procedure related risks may reasonably decline PFO closure.
- 2.3.** In patients with a history of atrial fibrillation (AF) who have had an ischemic stroke, the SCAI guideline panel suggests against the routine use of PFO closure (conditional recommendation, very low certainty of evidence).
- 2.4.** In patients with thrombophilia on antiplatelet therapy and not anticoagulation therapy and who have had a prior PFO-associated stroke, the SCAI guideline panel suggests PFO closure rather than antiplatelet therapy alone (conditional recommendation, very low certainty of evidence).
- REMARK:** Patients who place lower value on the uncertain benefits of PFO closure and a higher value on the possible procedure related risks may reasonably decline PFO closure.
- 2.5.** Patients with high-risk anatomy (i.e., ASA) - refer to Recommendation 2.1
- 2.6.** Patients evaluated with a RoPE score - refer to Recommendation 2.1
- 2.7.** The SCAI guideline panel makes no recommendation regarding PFO closure based on prolonged time since stroke (no recommendation, knowledge gap).



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### 3 Recommendations for adults with a prior PFO-associated stroke: percutaneous PFO closure versus anticoagulation therapy



- 3.1.** In patients between the ages of 18 and 60 with a prior PFO-associated stroke and no other indication for treatment with anticoagulation, the SCAI guideline panel suggests PFO closure plus antiplatelet therapy rather than anticoagulation therapy alone (conditional recommendation, low certainty of evidence).
- REMARK:** This recommendation is independent of patient anatomy (i.e., presence of ASA, size of shunt) due to limited clinical data on these sub-populations. A RoPE score  $\geq 7$  may identify patients who are likely to receive greater benefit from PFO closure.
- 3.2.** In patients 60 years or older with a prior PFO-associated stroke and no other indications for treatment with anticoagulation, the SCAI guideline panel suggests PFO closure plus antiplatelet therapy rather than long-term anticoagulation therapy alone (conditional recommendation, very low certainty of evidence).
- REMARK:** Patients in this age group who place a lower value on the uncertain benefits of PFO closure and a higher value on the possible procedure related risks may reasonably decline PFO closure.
- 3.3.** Patients with high-risk anatomy (i.e., ASA) - refer to Recommendation 3.1
- 3.4.** Patients evaluated with a RoPE score - refer to Recommendation 3.1
- 3.5.** The SCAI guideline panel makes no recommendation regarding PFO closure based on prolonged time since stroke (no recommendation, knowledge gap).

## 4 Recommendations for adults with a prior PFO-associated stroke and other indications for longterm anticoagulation



### 4.1.

In patients with thrombophilia and a prior PFO-associated stroke, the SCAI guideline panel suggests PFO closure in addition to lifelong antithrombotic therapy rather than antithrombotic therapy alone (conditional recommendation, very low certainty of evidence).

**REMARK:** Patients who need long term anticoagulation and who place a lower value on the uncertain benefits of PFO closure and a higher value on the possible procedure related risks may reasonably decline PFO closure.

### 4.2.

In patients with a history of DVT requiring lifelong anticoagulation and a concomitant PFO-associated stroke, the SCAI guideline panel suggests PFO closure plus lifelong anticoagulation rather than lifelong anticoagulation alone (conditional recommendation, very low certainty of evidence).

**REMARK:** Patients who need lifelong anticoagulation and who place a lower value on the uncertain benefits of PFO closure and a higher value on the possible procedure related risks may reasonably decline PFO closure.

### 4.3.

In patients with a history of pulmonary embolism (PE) requiring lifelong anticoagulation and a concomitant PFO-associated stroke, the SCAI guideline panel suggests PFO closure plus lifelong anticoagulation rather than lifelong anticoagulation alone (conditional recommendation, very low certainty of evidence).

**REMARK:** Patients who need lifelong anticoagulation may place a lower value on the uncertain benefits of PFO closure and a higher value on the possible procedure related risks and may reasonably decline PFO closure.



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## 5 Recommendations for post-procedure management of patients undergoing percutaneous PFO closure

- 5.1.** The SCAI guideline panel makes no recommendation regarding duration beyond one month of dual antiplatelet therapy after PFO closure (no recommendation, knowledge gap).



## References

1. Clinical Practice Guidelines We Can Trust. *Clinical Practice Guidelines We Can Trust*. 2011:1-197.
2. Qaseem A, Forland F, Macbeth F, et al. Guidelines International Network: Toward International Standards for Clinical Practice Guidelines. *Ann Intern Med*. Apr 3 2012;156(7):525-U103. doi:10.7326/0003-4819-156-7-201204030-00009
3. Schunemann HJ, Wiercioch W, Etzeandia I, et al. Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise. *CMAJ*. Feb 18 2014;186(3):E123-42. doi:10.1503/cmaj.131237
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