AAN Summary of Practice Advisory for Patients and Their Families

Practice Advisory Update of Practice Parameter: Recurrent Stroke with Patent Foramen Ovale

This information sheet is provided to help you understand the evidence* for recurrent stroke with patent foramen ovale (PFO). It is a service of the American Academy of Neurology (AAN).

The AAN is the world’s largest association of neurologists and neuroscience professionals. Neurologists are doctors who identify and treat diseases of the brain and nervous system. The AAN is dedicated to promoting the highest quality patient-centered neurologic care.

Experts carefully reviewed the available scientific studies on recurrent stroke in patients with a PFO. The following information is based on evidence from those studies and other key information. The information summarizes the main findings of the 2016 AAN practice advisory on PFO and recurrent stroke. This advisory updates the 2004 practice parameter (guideline) on PFO and atrial septal aneurysm (ASD) in recurrent stroke.

To read the full 2016 practice advisory, visit AAN.com/guidelines.

Overview

The AAN has updated its 2004 guideline on the management of patients with a heart defect called a PFO who have had an ischemic stroke or TIA (transient ischemic attack) of unknown cause. An ischemic stroke is a stroke caused by a blockage in an artery in the brain, usually by a blood clot. The clot may have formed in the brain or in another part of the body and traveled to the brain. TIAs are episodes of temporary symptoms similar to stroke symptoms but without permanent injury seen on brain imaging.

According to the practice advisory, PFO closure should not be routinely recommended to patients with ischemic stroke. This advisory is intended to increase awareness that PFO is common and that the rate of recurrent strokes from this condition is low.

What is a PFO? Is this a common condition?

A PFO is a normal hole in the fetal heart that is present in all people when they are developing in the womb. The hole is in the wall separating the upper chambers (left and right atria) of the heart. Normally, this hole closes on its own after birth, but in some instances, the hole remains open throughout adulthood. This condition typically does not lead to a problem for the majority of people with a PFO.

What therapies are available for the treatment of a PFO?

A PFO is common and occurs in about one in four adults. According to scientific studies, a PFO presents a low risk for stroke. However, in some cases, clinicians and patients will decide to seal the hole with a closure device. This prevents the flow of blood between the upper chambers of the heart. This procedure is known as a PFO closure.

There are two medical devices (AMPLATZER PFO Occluder and STARFlex) that have been tested to reduce the risk of stroke in randomized trials. However, the STARFlex is not available for use, and the AMPLATZER PFO Occluder is currently under review by the US Food and Drug Administration (FDA). Clinicians will sometimes use other devices off-label (without FDA approval) to close the hole in the heart.

In a PFO closure, a long, hollow tube called a catheter enters a vein—usually through a small cut in the inner thigh—that leads into the heart. The closure device passes through the catheter and forms a seal to close the hole. This stops blood from flowing between the two chambers.

At the time of this writing, PFO closure using one of these devices in the United States will likely cost $15,000 or more.
What does the research say about PFO closure for preventing recurring strokes?

The experts are not yet certain of the best approach to prevent another stroke. Typical prevention measures include medication to reduce blood clots. The advisory recommends that aspirin or other antiplatelet drugs (medications that keep blood clots from forming) be used instead of anticoagulant drugs such as warfarin. However, there may be a strong reason to use an anticoagulant if a person has a history of blood clots in the legs or lungs, or tendency to get blood clots. Compared with typical prevention measures for secondary stroke, closure devices have limited evidence to support their use. The advisory concludes that having a PFO is a low risk for stroke. Thus, in many cases, patients should not have their PFOs closed.

There are rare but serious risks linked to PFO closure. With the AMPLATZER PFO Occluder and STARFlex, there is low evidence* of an increased risk of an irregular heartbeat associated with a risk of stroke. There is also moderate evidence* of procedure-related difficulties.

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*After the experts review all of the published research studies, they describe the strength of the evidence supporting each recommendation:
- Strong evidence = Future studies very unlikely to change the conclusion
- Moderate evidence = Future studies unlikely to change the conclusion
- Low evidence = Future studies likely to change the conclusion
- Very low evidence = Future studies very likely to change the conclusion

This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

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