卵円孔開存患者においてデバイスが転帰を改善する (Abstract 18-LB-18898-ACC)

DEFENSE-PFO：デバイスによる閉鎖は潜在性脳卒中後の再発を予防する

DEFENSE-PFO: Device closure prevents secondary strokes after cryptogenic stroke

卵円孔開存（PFO）患者のうち、脳卒中後に開存閉鎖デバイスを植え込まれた者は、薬物療法のみの患者に比べ転帰が良好であった。この結果はAmerican College of Cardiology's 67th Annual Scientific Session で発表され、*Journal of the American College of Cardiology* に掲載された。オープンラベルトライアルであるDEFENSE-PFOにおいて、PFO患者120人がカテーテルによる経皮的PFO閉鎖術と薬物療法の併用、または薬物療法単独群にランダムに割り付けられた。2年間の追跡調査中に、主要評価項目を発現した者は閉鎖術併用群ではいなかったが、薬物療法単独群では6人（13.0%）であった（p=0.013）。

Full Text

Among people with a patent foramen ovale (PFO), those who received a medical device to close this opening after a stroke fared better after two years compared with those who received stroke-preventing medications alone. These findings from a study presented at the American College of Cardiology's 67th Annual Scientific Session and support the results of several similar trials in recent years and suggest patients with a high-risk PFO are likely to benefit most from the device. This study was simultaneously published online in the *Journal of the American College of Cardiology* at the time of presentation.

An estimated 1 in 4 people have a PFO, though many are undiagnosed. The condition does not typically cause symptoms but may increase the risk of stroke.

Among patients younger than 55 years of age who experience a cryptogenic stroke the prevalence of PFOs has been found to be around 46 percent, much higher than the rate of PFOs in the general population. The new findings add to a growing body of evidence that closing the PFO after this type of stroke can help prevent subsequent strokes and related problems, particularly in those with a high-risk PFO.

Researchers stopped enrollment for the trial early after determining, based on the results of several recent trials, that it would be unethical to continue assigning some patients to not receive the PFO closure device in light of mounting evidence of its clear benefits. Despite the smaller-than-expected number of participants, researchers said the new trial helps clarify which patients are likely to benefit most from the medical device based on the physical characteristics of their PFO.

"Considering the high prevalence of PFO in the general population and cryptogenic stroke patients, the key to appropriate use of this medical device is determining how to select optimal candidates for the procedure," said Jae Kwan Song, MD, a cardiologist at Asan Medical Center in Seoul, South Korea and the study's lead author. "Our study showed that the potential benefit from closure can be determined on the basis of the size of the PFO and the movement of the heart wall around the PFO."

In the open label, DEFENSE-PFO trial, 120 patients with PFO were randomized to receive transcatheter PFO device closure plus medical therapy (n=60) or medical therapy alone (n = 60). High-risk PFO was defined as PFO with atrial septal aneurysm, hypermobility or PFO size ≥2 mm. Medical therapy included anticoagulants or antiplatelet drugs as determined by the patients' physicians. No direct oral anticoagulants were used in the study. The primary endpoint was a composite of stroke, vascular death or TIMI-defined major bleeding during the two-year follow-up.

Researchers followed patient outcomes for two years. The study's primary endpoint was a composite of stroke, major bleeding events and death from vascular causes.

No primary endpoint events occurred in the device closure group during follow-up, compared with six events (2-year event rate, 13.0 percent; standard error, 5.0) in the medical therapy alone group (log-rank p = 0.013). Transient ischemic attack was reported in one patient receiving medical therapy alone. Procedural complications in the device closure group included atrial fibrillation (n=2), pericardial effusion (n=1) and puncture site reaction (n=1).

"We believe that PFO closure should be done in selected patients with cryptogenic stroke and PFO," Song said. "With our study and other recent trials, the criteria for selecting patients for the procedure are becoming clearer; in particular, the results suggest that closure is beneficial for those with high-risk PFO."

There are several available medications to prevent blood clots in people who have experienced a stroke, including antiplatelet drugs, direct oral anticoagulants and traditional anticoagulants such as warfarin. Because trials for PFO closure devices have been inconsistent in their selection of medications, Song said additional studies are needed to clarify the potential benefits of different medications when used post-stroke in patients with PFO.

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